EXHIBIT 1

EXPERT REPORT

Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances

Prepared by
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I. QUALIFICATIONS AND EXPERIENCE

Statement of Qualifications

- 1999 graduate of Eastern Michigan University with a degree in Public Administration.
- 26 years of law enforcement experience.
- Retired in 2002 as an Executive Lieutenant with the Romulus Police Department.
- Drug Enforcement Administration Diversion Investigator assigned to the Detroit Divisional Office from September 2004 through retirement in June 2017. Diversion Investigators are responsible for several different types of investigations including regulatory investigations, state-action related investigations, pre-registration application investigations, civil investigations, administrative investigations, and criminal investigations. In 2011 Detroit DEA management restructured the responsibilities of the diversion investigators in the Detroit Divisional Office. At that time, Mr. Rafalski's primary responsibility was to conduct administrative, civil, and regulatory investigations of DEA registrants.
- Successfully completed the following DEA training: Basic Diversion Investigator School (2004), Distributor Briefing/Training (2008), Advanced Diversion Investigator School (2009), Comprehensive Regulatory Investigation Training (2010), Diversion Leadership School (2011), Advanced Diversion Investigator School (2015).
- Participated as a DEA Instructor in the design and presentation of the following training programs: Task Force Officers Training and Orientation, Detroit, Michigan (January 2009), Basic Narcotics Training, Macomb Police Academy, Clinton Township, Michigan (April 2009), U.P. Prescription Diversion/Asset Forfeiture Class, Marquette, Michigan (July 2009 and September 2010), and Basic Narcotic Investigator Course, Richmond, Kentucky (May 2010). Prescription Drug Diversion, Gaylord, Michigan (2015)

Awards

- Maintained a performance rating of "Outstanding" from 2005 to 2016.
- Received DEA performance awards from 2009 to 2015 and in 2017.
- Received an award from the Detroit Federal Executive Board in 2013 for exemplary public service to the DEA.
- DEA Administrator's Award for the investigation of the Harvard Drug Group.

- In June of 2013 and September of 2017 he received recognition from the United States Attorney's Office, Eastern District of Michigan for the Harvard Drug Group and Mallinckrodt LLC

Significant Investigations

- **2004 -2008 Investigation of Dr. Leo Ognen**
  - Criminal opioid investigation related to improper prescriptions.
  - Led to the creation of prescribing database utilized in Ohio.
  - Conducted interviews with employees of pharma companies.
  - Resulted in conviction and incarceration.

- **2006 – 2011 Investigation of Dr. Sohrab Shafinia, D.O.**
  - Criminal opioid investigation of conspiracy to possess controlled substances with intent to distribute.
  - Investigation led to the identification and conviction of an organized prescription drug ring.
  - Extensive reviews of Michigan Automated Prescribing Records (MAPS)
  - Conducted interviews, surveillance, recruiting and utilizing cooperating individuals, as well as undercover activities.
  - Investigation led to the identification and conviction of the responsible pharmacist.

- **2006 – 2008 Investigation of Dr. Louis Cannella, M.D.**
  - Criminal opioid investigation related to improper prescriptions.
  - Extensive reviews of Michigan prescription monitoring program records.
  - Led to the creation of a Wisconsin prescription database.
  - Conducted numerous interviews of witnesses and defendants, surveillance, recruiting and using cooperating individuals, as well as other investigative activities.
  - Resulted in conviction and incarceration.

- **2006 Regulatory Investigation of Walgreen, Perrysburg, Ohio**
  - Unannounced regulatory investigation related to ensure compliance with regulations and record keeping involving controlled substances.
  - Conducted an accountability audit, record-keeping review, and security investigation.
  - Resulted in the issuance of a Letter of Admonition for inadequate SOMS.

- **2007 Regulatory Investigation of Lake Erie Medical Supply**
  - Regulatory investigation related to repackaging, relabeling and distribution of controlled substances mainly to physicians and medical offices.
  - Recommended a distributor briefing at DEA headquarters in November 2008 to reiterate regulatory requirements to registrants.

- Attended the November 2008 distributor briefing presented by other Diversion Investigators.

- **2010 – 2011 Administrative Investigation of The Harvard Drug Group**
  - Conducted a review of ARCOS data to identify any unusual patterns of distribution of oxycodone to Florida pain clinics.
  - Conducted extensive review of company records and policies, controlled substance order forms, DEA Form 222s, and interviews of employees.
  - Conducted review of chargeback system.
  - Investigation led to an Order to Show Cause in June of 2010 for among other things, developing work around as to not trigger SOMS.
  - Investigation concluded with entry of an Administrative Memorandum of Agreement that remained in effect for three years.

- **2010 – 2013 Administrative Investigation of Masters Pharmaceutical**
  - Met with and interviewed employees and initiated an on-site investigation.
  - Served several DEA Administrative subpoenas and obtained 21 customers files to review.
  - Reviewed customer files which contained customer due diligence including but not limited to: questionnaires, on-site investigation reports, written notations, utilization reports, ship to memos, SOMS information, and electronic notations.
  - Investigation concluded with the issuance of an Order to Show Cause.
  - Order to Show Cause resulted in revocation of DEA registration which was affirmed by United States Court of Appeals for the District of Columbia Circuit.

- **2010 – 2017 Administrative Investigation of Mallinckrodt L.L.C.**
  - Administrative investigation begun in response to information related to a chargeback program based on other investigations.
  - Reviewed the chargeback discount program and transactional information involved in the program, which included the purchasers name, address, type and strength of drug, and date of transaction.
  - The investigated chargeback data contained information that allowed Mallinckrodt to see the geographic distribution of their products, the volume and size of purchases.
  - Chargeback data also disclosed some pharmacies and/or practitioners utilizing multiple distributors to purchase the same product in large quantities.
  - Through an administrative subpoena requested documents related to suspicious order system and related policies, related compliance policies, chargeback data, customer files, internal and external communications to include emails, written correspondence, and notes.

- Administrative investigation resulted in an Administrative Memorandum of Agreement that remained in effect for three years.

As a DEA Diversion Investigator with 13 years of experience (2004-2017), I am uniquely qualified to offer expert opinions regarding compliance with federal regulations governing the distribution of controlled substances including oxycodone and hydrocodone. I am familiar with the DEA Diversion Investigators Manual and received training from the United States Department of Justice on suspicious order monitoring, data analysis from ARCOS, reporting of suspicious orders and the due diligence required before shipping an order flagged as suspicious. I directly participated in the successful prosecution of Masters Pharmaceutical which resulted in a case opinion from the highest federal court in the country (to date). I led the first action that led to a memorandum of agreement with a manufacturer for failure to maintain effective controls to prevent diversion and failing to design and operate an adequate suspicious order monitoring system.

Based (a) on my education, training and experience, (b) the law, regulation and practices in the area of CSA enforcement, and (c) on my review of document and testimony provided in this case (MDL 2804), I am of the opinion to a reasonable degree of professional certainty that there was a systematic, prolonged failure over many years by the defendant manufacturers and distributors to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market.[1] I am further of the opinion that this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Cuyahoga County and Summit County. I am prepared to testify regarding the regulatory duties imposed by the CSA and federal regulations. I have been asked to review the documents produced by the defendants and depositions taken in MDL2804 and offer opinions regarding statutory and regulatory compliance.

I offer my opinions herein to a reasonable degree of professional certainty. I believe the facts stated herein are true and accurate and based on the record provided to me. I understand that the defendants continue to supplement discovery and have disclosed tens of millions of documents. I have relied upon the defendant's answers to Combined Discovery Requests (served on July 1, 2018) as a basic outline for evidence of compliance to reach my opinions.

I am being compensated at the rate of $300.00 per hour for the time I have spent related to this report. The hourly rate for my time spent testifying is $500.00 per hour. I have not previously provided expert testimony at trial or deposition. I have not authored any publications or articles. In addition to the documents and testimony cited within my report, I have also reviewed documents identified in the attached Schedule I.

[1] I provide all opinions in this report with a reasonable degree of professional certainty.

II. STANDARDS

A. STATUTORY DUTY.

Each distributor owes a duty to ***maintain effective control*** against diversion of prescription opiates into the illicit market. 21 U.S.C.A. § 823(b)(1) [1970].

The Controlled Substances Act ("CSA") and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009). The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.[2]

The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market.[3] Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA.[4]

The CSA provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain ***illegal***.[5] "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic."[6]

Distributors of Schedule II drugs—controlled substances with a "high potential for abuse"[7] – must maintain "effective control against diversion of particular controlled substances into other

[2] *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005) (internal citations omitted).

[3] H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970); *see* 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880.

[4] 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

[5] 1970 U.S.C.C.A.N. 4566, 4569 (emphasis added).

[6] *United States v. Moore*, 423 U.S. 122, 135 (1975).

[7] 21 U.S.C. §§ 812(b), 812(2)(A)-(C)

than legitimate medical, scientific, and industrial channels."[8] The CSA is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. **Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[9] The CSA seeks, through appropriate regulation of the manufacture and distribution of drugs, to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses.[10]

Based on my review of all the relevant documents and testimony taken in this case (MDL 2804) it is my opinion to a reasonable degree of professional certainty that the multiple distributors servicing Cuyahoga County and Summit County failed to maintain effective control against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels in violation of 21 U.S.C.A. § 823(b)(1). The bar graphs included as Figures 1 and 2 in Schedule II evidence the volume of hydrocodone and oxycodone distributed into Cuyahoga County and Summit County from 1996 to 2018.

B. REGULATORY DUTY

Each distributor "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[11]

This regulatory duty has been defined to include the following obligations:

> The "***security requirement***" at the heart of this case mandates that distributors "design and operate a system" to identify "suspicious orders of controlled substances" and report those orders to DEA (the ***Reporting Requirement***). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor provide basic information about certain orders to DEA, so that DEA "investigators in the field" can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out "potential illegal activity." *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007). Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some

[8] 21 U.S.C. § 823(b)(1).

[9] 1970 U.S.C.C.A.N. 4566, 4571-72.

[10] 1970 U.S.C.C.A.N. 4566, 4574.

[11] 21 C.F.R. § 1301.74(b) [1971]

> "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the ***Shipping Requirement***).[12]

The regulatory duty is not difficult to follow and understand. As one who voluntarily applies to become a registrant must submit an application and undergo a pre-registration investigation. The pre-registration investigation involves a through onsite inspection of the registrant's facilities as well as extensive discussions of the applicable regulations and the security requirements that must be followed. While there are numerous requirements related to registration, my opinions focus on the following compliance requirements:

- Maintain effective controls to prevent the diversion of controlled substances into "other than legitimate medical, scientific, and industrial channels";
- "Design and operate" a system to identify suspicious orders; and
- Report suspicious order "when discovered."

C. MDL2804 Discovery Ruling 12

The Court in MDL2804 issued a discovery ruling (Discovery Ruling 12) which outlines the statutory and regulatory duties imposed by federal law upon distributors of controlled substances.[13] The ruling addresses the following legal standards:

> Distributors of opioids are required to "'design and operate a system' to identify 'suspicious orders of controlled substances' and report those orders to DEA (the Reporting Requirement)." *Masters Pharmaceutical*, 861 F.3d 206, 212 (D.C. Cir. 2017) (quoting 21 C.F.R. § 1301.74(b)). Federal regulations explain that "suspicious orders include [among others] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). Thus, an order for opioids received by a distributor from a retail pharmacy may qualify as "suspicious" for any of a number of different reasons.[14]

[12] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017) (emphasis added).

[13] See Discovery Ruling No. 12 regarding Suspicious Order Interrogatory [Doc. 1174].

[14] "Of course, an order may be suspicious for other reasons, even if it doesn't fit the Monthly Total Rule, such as that the pharmacy-customer "submitted more order forms in a 30-day period than it had in any of the prior six calendar months [the 'Order Form Rule'], or if the timing of the order did not comport with the customer's general ordering pattern over those six months [the 'Order Timing Rule']." *Id.* There are many other algorithms a distributor could use to identify opioid orders as suspicious, including: (1) the order for the opioid was placed within 30 days of an earlier suspicious order for the same opioid (the "Consecutive Order Rule"); (2) the order for the opioid was placed within 30 days of an order for the same opioid from a different distributor (the "Multi-Distributor Rule"); (3) the percentage increase in the amount of opioid ordered exceeded a certain threshold (the "Percentage Increase Rule"); or (4) the amount of opioid ordered exceeded by some threshold the amounts ordered by other similar or nearby pharmacies ("the Pharmacy Comparison Rule").

"*See also Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) ("a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency. In other words, orders placed by a pharmacy that engages in suspicious activity, but places orders of regular size, pattern, and frequency, could still be deemed suspicious."); *id.* at *55478 (noting that "suspicion" is a low bar: it "is simply a far lower standard of

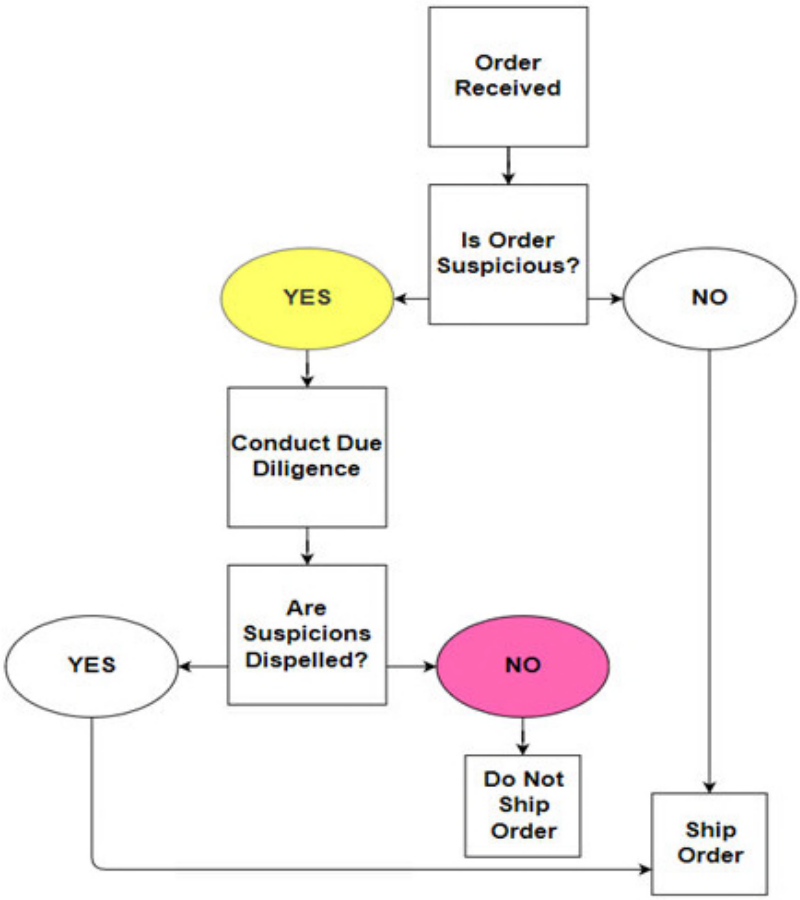
The simplest example is that a given order for an opioid may be suspicious if it was of "unusual size" – say, an order that pushed a pharmacy's monthly total number of opioid doses to exceed the monthly totals the same pharmacy had ordered in the prior six months. The Order refers below to this algorithm as the "Monthly Total Rule." (*Masters Pharmaceutical* described the "Monthly Total Rule" as follows: an order is suspicious if "that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months." *Id.* at 213.)

As noted, once it has identified a suspicious order, a distributor is required to report it to the Drug Enforcement Agency ("DEA"). *See* 21 C.F.R. §1301.74(b) ("The [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the [distributor]."). Furthermore, having received a suspicious order, the distributor "must make one of two choices: decline to ship the [suspicious] order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Id.* at 212–13. Of course, a distributor's due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed." *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) (hereinafter, "*Decision and Order*"). Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence." *Masters Pharmaceuticals*, 861 F.3d at 212.[15]

proof than whether it is 'likely' that the circumstance exists," and "the regulation's adoption of suspicion as the threshold for triggering the requirement that a distributor inform the Agency about the order does not even rise to the level of probable cause.")" Discovery Ruling No. 12, fn 2.

[15] Discovery Ruling No. 12 [Doc. 1174]. *See also, id.*, at n.3 ("The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the *Decision and Order*.")

The Order noted the "legal authorities reviewed above leave unclear exactly when an order is deemed suspicious, and thus when a distributor is required to inform the DEA that it received a suspicious order. The following flowchart illustrates the issue."[16]



This flowchart shows how a distributor's Suspicious Order Monitoring System must work and diagrams the process a distributor must undertake when it receives a suspicious order. Notably, there is a "yellow light" (caution) and a "red light" (stop) in the process. When a distributor first identifies an order as suspicious, this is a "yellow light" – it cannot ship the order without doing some investigation. If that investigation does not "dispel all red flags indicative that a customer is engaged in diversion," then the distributor gets a "red light" and must not ship the order. *Masters Pharmaceutical*, 861 F.3d at 222. Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ("SOMS"), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence

[16] *See* Discovery Ruling No. 12 issued December 9, 2018 at page 5.

efforts are required when investigating an order after it is identified as suspicious. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; it is free to design its SOMS using any algorithms and rules it believes will get the job done.

With regard to the Reporting Requirement, it is not entirely clear whether a distributor's obligation to inform the DEA attaches: (1) when the "yellow light" flashes – that is, when the distributor first identifies an order as suspicious; or (2) only after the "red light" flashes – which would mean a distributor does not have to inform the DEA it received a suspicious order if investigation shows the order was legitimate, after all. Indeed, the authorities cited above provide support for each approach, as shown by the following quotations.

"Red Light"

- "[I]f, ***even after investigating the order***, there is any remaining basis to suspect that a customer is engaged in diversion; the order must be deemed suspicious and the Agency must be informed. *Decision and Order*, 80 Fed. Reg. at *55478.

- "DEA regulations expressly provide that deviations in size, frequency, or pattern are the sort of indicia that give rise to a suspicion and, ***unless the suspicion is dispelled***, the obligation to report. *Masters Pharmaceuticals*, 861 F.3d at 215 (citing *Decision and Order*, 80 Fed. Reg. at *55,479; and 21 C.F.R. §1301.74(b)).

"Yellow Light"

- "***Once a distributor has reported a suspicious order***, it must make one of two choices: decline to ship the order or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Masters Pharmaceutical*, 861 F.3d at 212–13.[17]

In other words, the Court determined it is unclear whether an order is "suspicious" (and so must be reported to the DEA) as soon as a distributor's SOMS flags it as suspicious, or only after due diligence fails to dispel any suspicion. In any event, it is clear that distributors are required to identify suspicious orders from pharmacies and cannot ship those orders unless they conduct "due diligence" that determines those orders are not likely to be diverted. Further, distributors are required to report suspicious orders to the DEA upon discovery.

[17] Discovery Ruling No. 12 [1174].

D. ARCOS/DADS

The Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)[18] system is used to track and report the transfer of pharmaceuticals and to detect potential diversion. This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970[19] and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971.[20]

The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispenser level.[21]

The information contained in the ARCOS system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to the pharmacies. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, sales, and purchase orders, and includes, but not limited to the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, NCD code, and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances.

All automated data files associated with ARCOS/DADS are maintained in the Department of Justice Data Center and the Drug Enforcement Administration Data Center and the system is

[18] "ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.). by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. *See* United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), *Background: What is ARCOS and What Does it Do?*, https://www.deadiversion.usdoj.gov/arcos/#background (last visited September 7, 2017)

[19] (21 U.S.C. 826(d))

[20] 69 FR 51104-02.

[21] *See* ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, *ARCOS Defined* (Version 1.0 August 1997).

located at Drug Enforcement Administration, 700 Army Navy Drive, Arlington, VA 22202. 69 FR 51104-02.

The ARCOS/DADS system uniquely has access to ***all*** of the data submitted by each DEA registrant from the across the country.[22] These distribution transactional records are compiled by the DEA through a portal and the data is compiled by DEA in accordance with law for determining quota, distribution trends, internal audits, inspection, investigations and other analyses.[23] Additionally, the DEA provides internet access to summary data from this system.

The DOJ/DEA disclosed the national ARCOS database to the Plaintiffs' Executive Committee (2006-2014) and that additional transactional data was independently disclosed by some of the defendants. Both sets of data were then uploaded to a database managed by Craig J. McCann, PhD, CF, of Securities Litigation and Consulting Group, Inc. ("SLCG") (retained as an expert by the PEC). I have relied upon data derived from and provided by SLCG in the formulating of specific requests.

The ARCOS data, defendant transactional data, and the SLCG reports generated therefrom are consistent with the types of data, facts, information, and reports I would typically rely on in conducting the analysis and reaching the opinions contained herein. I am very familiar with the ARCOS data and defendant transactional data and have experience analyzing the data and reports generated therefrom. I have reviewed SLCG's methods and reports and they are consistent with my understanding, based on my experience, of how the data should be analyzed.

E. DEA DIVERSION INVESTIGATOR'S MANUAL.

The DEA published a manual which provides further guidance related to the statutory and regulatory duties. Portions of the manual have previously been publicly available and accurately set forth the charge for DEA investigator as follows:

> Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. ***The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.*** An

[22] The DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. *Keysource Med., Inc. v. Holder*, No. 1:11-CV-393, 2011 WL 3608097, at *2 (S.D. Ohio Aug. 16, 2011).

[23] https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html

> investigation will be conducted for possible violation of the CSA and regulations upon determining that the reporting registrant, as a general practice, does not voluntarily halt shipments of controlled substances to registrants involved in suspected diversion or to registrants against whom previous action has been taken. In these instances, the registrant is subject to the appropriate prosecution and/or administrative action.[24]

Importantly, the DEA does not approve or disapprove supplier shipments of controlled substances. The responsibility for making the decision to ship rests with the supplier.[25] [26]

F. DEA DISTRIBUTOR INITIATIVE BRIEFINGS.

In August 2005, Drug Enforcement Administration designed and implemented the DEA Distributor Initiative. The initiative was in response to the growing number of rogue Internet pharmacies illegally dispensing controlled substances and their pattern of purchasing extremely large amounts of a limited type of controlled substances from distributors. This program consisted of an individual meeting between the DEA and distributors to re-iterate to DEA registrants their responsibilities under the Controlled Substances Act and Code of Federal Regulations and to discuss current trends and methods of diversion.

In February 2014, at a conference in North Carolina, DEA Deputy Assistant Administrator Joseph T. Rannazzisi reported that the DEA had conducted distributor briefings to 81 registrants that had a total of 233 registered locations. The DEA has produced in discovery summaries of some of these meetings as follows:

> Memorandum, Meeting with Cardinal Health, Inc. Concerning Interact Pharmacies on August 22, 2005;[27]
>
> Memorandum, Conference Call with. Mr. John. Gilbert of McKesson Corp. on November 28, 2005;[28]

[24] *See* DEA Diversion Investigators Manual (1996) (CAH_MDL2804_02203353, CAH_PRIORPROD_DEA07_01176914 at 01176957) ; *see also* DEA Diversion Manual (1990) (CAH_PRIORPROD_DEA_01176247 at 01176301); DEA Diversion Investigators Manual (2011) (CAH_MDL2804_00953317 at 00953396, CAH_MDL2804_01483146, CAH_MDL2804_01563592) ("By its very nature, an order is a request to purchase controlled substances and has not yet been filled. Reporting a filled order is potentially allowing controlled substances to be diverted. Therefore, suspicious orders will not be filled.")

[25] See DEA Diversion Investigators Manual (1996) (CAH_MDL2804_02203353, CAH_PRIORPROD_DEA07_01176247); see also DEA Diversion Investigators Manual (2011) (CAH_MDL2804_00953317, CAH_MDL2804_01483146, CAH_MDL2804_01563592) ("DEA field offices will not approve or disapprove a registrant's shipment of controlled substances, nor their procedures for detecting suspicious orders. The responsibility for detecting suspicious orders and making the decision to ship rests solely with the registrant.")

[26] At the request of DEA/DOJ, Plaintiffs have removed a section of this Report based on DEA/DOJ's claim that a claw-back of a document cited in the removed section is forthcoming.

[27] US-DEA-00000352.

[28] US-DEA-00000369.

Memorandum, Meeting Between Office of Diversion Control (OD) and McKesson Corp. on January 3, 2006;[29]

Memorandum, Internet Presentation; with AmerisourceBergen on August 10, 2005;[30] and

Memorandum, Distributor Initiative Briefing with AmerisourceBergen Drug on May 16, 2017.[31]

At these briefings DEA personnel would reiterate the registrant's requirement to maintain effective controls to prevent diversion as required in U.S.C. 21 § 843(e) and 21 C.F.R. § 1301.71(a). During these meetings the DEA specifically focused on discussing 21 C.F.R. § 1301.74(b) which states, "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." DEA also advised the registrant at these meetings that DEA cannot tell a distributor if an order is legitimate or not.[32] The distributor has the responsibility to determine which orders are suspicious and once identified they should report those orders to DEA and should not distribute suspicious orders.[33] Further, it was reiterated that a distributor was advised prior to shipping any order that was determined to be suspicious, the distributor should conduct a due diligence investigation to insure the controlled substances in the order are not likely to be diverted and document their due diligence actions.[34] Failure to do so could result in action against their DEA registration.

G. DEA GUIDANCE LETTER

(September 2006) - Written notification issued to distributors and manufacturers from DEA Deputy Assistant Administrator Joseph T. Rannazzisi.[35]

In September 2006, in response to the nationwide growing health problems involving diversion of controlled substances, DEA Deputy Assistant Administrator Joseph T. Rannazzisi forwarded a letter to all DEA registered distributors and manufacturers. The purpose of the letter

[29] US-DEA-00000371.

[30] US-DEA-00000147.

[31] US-DEA-00000144

[32] US-DEA-00000352, 00000360.

[33] *Id.*

[34] *See also Novelty Distributors, Inc.*, 73 Fed. Reg. 52,689, 52,669 (Drug Enf't Admin. September 3, 2008) ("Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for legitimate purposes.")

[35] *See* CAH_MDL_PRIORPROD_DEA07_00837645.

was to reiterate the legal duties of distributors as DEA registrants and provide some examples of activities that may be indicative of diversion.

Mr. Rannazzisi's letter referenced 21 U.S.C. 823(e) that restated the requirement that distributors and manufacturers have a legal requirement to maintain effective controls against diversion. Mr. Rannazzisi's letter further cited DEA Regulation 21 C.F.R. 1301.74(b) which states the requirement for a registrant to design and operate a system to disclose suspicious orders of controlled substances and to report suspicious orders to the D.E.A. when discovered. The system should be capable of identifying a suspicious order based on size, pattern and frequency and reporting that order to DEA. Contained in the written notification were a list of circumstances that may be indicative of diversion. Those circumstances listed the following:

a. Ordering excessive quantities of a limited variety of controlled substances

b. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered.

c. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.

d. Ordering the same controlled substances from multiple distributors.

The written communication also listed some guidance for a distributor by providing some possible inquiries of a customer's business activity that could be indicative of diversion. Mr. Rannazzisi further stated and reiterated:

> The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):
>
> > The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
>
> It bears emphasis that the foregoing ***reporting requirement is in addition to, and not in lieu of the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.***
>
> This, in addition to reporting all suspicious orders, ***a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels***. Failure to exercise such due diligence could, as circumstances

warrant, provide a statutory basis for revocation or suspension of a distributor's registration.[36]

H. JUNE 2007 SOUTHWOOD PHARMACEUTICALS, INC. DISTRIBUTOR CASE

DEA Deputy Administrator Michele M. Leonhart issued an Order on June 22, 2007[37], detailing the revocation of DEA registration for Southwood Pharmaceuticals, Inc ("Southwood"). The Order further denied any pending applications for renewal or modification of registration because of the imminent danger to the public health or safety.

The language contained in this Order clearly re-iterated the requirement for a distributor to have a suspicious order monitoring program. The Order states the following, "a registrant must ''design and operate a system to disclose to the registrant suspicious orders of controlled substances''; suspicious orders must be reported to the local Field Division Office upon discovery by the registrant.[38] Under the regulation, suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.''

This Order also contains a description of the conduct of Southwood causing the revocation of their DEA registration as described in the Order to Show Cause and Immediate Suspension Order of Registration (OTSC/ISO) issued on November 30, 2006. The OTSC/ISO detailed that Southwood distributed controlled substances to customers they knew or should have known were diverting controlled substances. The OTSC/ISO stated Southwood repeatedly supplied excessive quantities of hydrocodone to fifteen pharmacies that were orders of unusual size and frequency as well as substantially deviating from the normal pattern. The OTSC/ISO further stated Southwood never reported any of the orders as suspicious to the DEA.

The OTSC/ISO also stated that Michael Mapes of the DEA conducted a meeting with Southwood by conference call on July 17, 2006. The content of the meeting described in the OTSC/ISO is consistent with the DEA Distributor Program being conducted by the DEA and described in this timeline. During this meeting Mr. Mapes discussed the purchasing activities of several pharmacies who were customers of Southwood. During this meeting Mr. Mapes also provided Southwood with a description of illegal conduct of Internet pharmacies and described factors to consider when assessing customers for diversion. These factors included the size and frequency of order, range of product order, and the percentage of control substances ordered when compared to non-controlled substances. Mr. Mapes further discussed the factors that are required to ensure a prescription is legally prescribed by a physician.

The following statement is contained in the OTSC/ISO, "a pattern of drugs being distributed to pharmacies [which] are diverting controlled substances demonstrates a lack of effective controls against diversion by the distributor" and could lead to the revocation of the distributor's registration." Mr. Mapes further stated, "… any distributor who was selling controlled

[36] *See id.* (emphasis added).

[37] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007).

[38] 21 CFR 1301.74(b).

substances that are being dispensed outside the course of professional practice must stop that distribution immediately."[39]

The OTSC/ISO stated Mr. Mapes discussed with Southwood representatives whether it could ship an order which it had reported as suspicious. Mr. Mapes advised Southwood representatives if they reported a suspicious order to the D.E.A. they still needed to make the decision as to whether to ship the order. The OTSC/ISO further detailed that Southwood representatives asked Mr. MAPES whether they should stop shipping controlled substances to the internet pharmacies and Mr. MAPES replied the DEA cannot tell a distributor whether a particular order is legitimate or not, and whether to ship was "a business decision," but Southwood had an obligation to ensure that the controlled substance being distributed were used for legitimate medical purposes.

I. DECEMBER 2007 DEA GUIDANCE LETTER

In December 2007, DEA Deputy Assistant Administrator for the Office of Diversion Control, Joseph T. Rannazzisi issued a second letter to all DEA registered distributors and manufacturers restating much of the information contained in the previous letter.[40]

This letter was focused on reiterating the responsibilities of manufacturers and distributors to inform DEA of suspicious orders as required by 21 CFR 1301.74(b)

The letter re-iterated that 21 CFR 1301.74(b) requires a manufacturer or distributor to design and operate a system to disclose to the registrant suspicious order of controlled substances. The letter further notified registrants it is the sole responsibility of registrants to design and operate the system. The letter advised registrants of the following, “Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for report suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The letter also notifies that filing a monthly report of transactions to the DEA, often referred to as excessive purchase reports, does not meet the regulatory requirement to report suspicious orders.

The letter also reiterated the following requirements:

1. 21 CFR 1301.74(b) requires DEA registrants inform the DEA of suspicious order when discovered by the registrant.
2. DEA registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine if the controlled substances are likely to be diverted.
3. The regulation states suspicious orders include orders of an unusual size, deviating substantially from a normal pattern, and orders of an unusual frequency. The criteria are disjunctive and are not all inclusive.

[39] *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 Fed. Reg. 36,487, 36,492(Drug Enf’t Admin. July 3, 2007).

[40] CAH_MDL_PRIORPROD_DEA07_00092296.

4. DEA registrants who routinely report suspicious orders, yet fill these orders without first determining whether the orders are not being diverted may be failing to maintain effective controls against diversion that may result in possible action against their DEA registration.

J. DEA ADMINISTRATIVE ACTIONS

Distributors and manufacturers in this industry regularly monitor DEA administrative actions involving maintenance of effective controls against diversion and failure to identify and/or report suspicious orders. There are many different types of sources that make the details of DEA administrative action available for the industry to review. The type of information available can be a very in-depth article or publications simple as a press releases. Two examples of an in-depth sources of information is the information published in the Federal Register involving DEA cases against Masters Pharmaceutical Inc. and Southwood Pharmaceuticals Inc.

The DEA posts administrative case information on the Internet on their website at www.deadiversion.usdoj.gov. The DEA and Department of Justice also normally issue press releases on administrative actions that subsequently generate media coverage and reviews by law firms. Further, trade organizations like HDA typically publish articles regarding DEA administrative action for review by their members. Typically, when a DEA administrative action occurs, there are several law firms that closely follow the industry and they post articles on their websites that describe the action and offer opinions of future impact to the industry.

Listed below are some of the significant administrative action against distributors and manufacturers for failing to maintain effective controls against diversion and for failing to identify and/or reports suspicious orders:

1. April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement and release agreement with the DEA related to the allegations made by the agency.[41]

2. June 22, 2007, the DEA revoked the Registration of Southwood Pharmaceuticals, Inc. 72 Fed. Reg. 36,487 (Department of Justice; Southwood Pharmaceuticals, Inc.; Revocation of Suspension (July 2, 2007)) on Tuesday, July 3, 2007July 3, 2007, Department of Justice, Drug Enforcement Administration article in the Federal Register, titled, Southwood Pharmaceuticals, Inc.; Revocation of Registration.[42]

[41] AmerisourceBergen Corporation, *AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of its Orlando Distribution Center's Suspended License to Distribute Controlled Substances*, June 22, 2007, available at http://investor.amerisourcebergen.com/news-releases/news-release-details/amerisourcebergen-signs-agreement-dea-leading-reinstatement-its (last visited March 11, 2019).

[42] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007)(*also available at* https://www.deadiversion.usdoj.gov/fed_regs/actions/2007/fr07032.htm (last visited March 10, 2019)).

3. November 29, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center which suspended their DEA registration for failure to maintain effective controls against diversion of hydrocodone.[43]

4. December 7, 2007, DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[44]

5. December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[45]

6. January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone. Cardinal agreed to suspend shipping any controlled substances from the location pending a resolution with the DEA.[46]

7. May 2, 2008, McKesson Corporation agree to pay a $13 million civil penalty and entered into an Administrative MOA with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.[47]

8. On September 30, 2008, Cardinal Health agreed to pay a $34 million civil penalty and entered into a Settlement and Release Agreement and Administrative Memorandum of

[43] Cardinal Health, Press Release, *Cardinal Health Receives DEA Order to Temporarily Cease Distribution of Controlled Substances from Auburn Wash. Facility*, November 29, 2007, available at (Source: https://ir.cardinalhealth.com/news/press-release-details/2007/Cardinal-Health-Receives-DEA-Order-to-Temporarily-Cease-Distribution-of-Controlled-Substances-from-Auburn-Wash-Facility/default.aspx (last visited March 11, 2019).

[44] Cardinal Health, Press Release, *Cardinal Health to Cease Distribution of Controlled Substances from Florida Facility*, December 7, 2007, available at https://cardinalhealth mediaroom.com/newsreleasearchive?item=122500 (last visited March 8, 2019).

[45] Drug Topics, "DEA hits third Cardinal Health distribution center," December 21, 2007, available at https://www.drugtopics.com/pharmacy/dea-hits-third-cardinal-health-distribution-center (last visited March 8, 2019).

[46] Drug Topics, "Cardinal caught between DEA and pharmacies over diversion control," April 14, 2008, available at https://www.drugtopics.com/community-practice/cardinal-caught-between-dea-and-pharmacies-over-diversion-control (last visited March 9, 2019).

[47] Settlement and Release Agreement and Administrative Memorandum of Agreement, entered into May 2, 2008, between DEA and McKesson Corporation, available at https://www.dea.gov/sites/default/files/ 2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf (last visited March 19, 2019).

Agreement (MOA) with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The MOA also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances.[48]

9. January 9, 2009, Rite Aid agreed to pay $5 Million in civil penalties to resolve allegations that Rite Aid knowingly filled prescriptions for controlled substances that were not issued for legitimate medical purposes; failed to notify the DEA of significant thefts and losses of controlled substances; failed to maintain or failed to furnish to the DEA upon request records required to be kept under the Controlled Substances Act for a period of two years; and failed to properly execute DEA forms used to ensure the amount of Schedule II drugs ordered by Rite Aid were actually received violations of the Controlled Substances Act in eight states.[49]

10. April 21, 2009, Settlement and Release Agreement and Administrative Memorandum of Agreement between DOJ/DEA and Masters Pharmaceutical Inc.[50]

11. June 15, 2010, Order to Show Cause – Immediate Suspension Order served to The Harvard Drug Group, Livonia, MI.[51]

12. June 10, 2010, DEA suspended Sunrise Wholesale, Inc. from selling controlled substances for supplying excessive amounts of oxycodone to "pill mills."[52]

13. October 13, 2010, settlement was reached between the DEA and CVS Pharmacy, Inc. resolving the criminal investigation of unlawful distribution and sales of pseudoephedrine ("PSE") by CVS/pharmacy stores in Southern California and Nevada and a CVS/pharmacy

[48] United States Attorney's Office. (October 2, 2008) *Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims That It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* [Press Release]. Available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html (last visited March 10, 2019).

[49] United States Department of Justice, (January 12, 2009) *Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations (last visited March 8, 2019).

[50] Settlement and Release Agreement and Administrative Memorandum of Agreement between DEA and Masters Pharmaceutical, Inc. Available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Masters%20Pharmaceutical%20-%202009.pdf (last visited March 19, 2019.

[51] Administrative Memorandum of Agreement between DEA and The Harvard Drug Group, LLC dated March 28, 2011. Available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Harvard%20Drug%20Group%20-%202011.pdf (last visited March 19, 2019).

[52] LaMendola, Bob. "DEA accuses Sunrise company of supplying painkillers to 'pill mills.'" Sun-Sentinel. June 22, 2010. Available at https://www.sun-sentinel.com/business/fl-xpm-2010-06-22-fl-drug-wholesaler-stopped-20100621-story.html (last visited March 19, 2019).

distribution center in Southern California. CVS paid a penalty of $75,000,000.00 and forfeited $2.6 million in profits for a total payment of $77.6 million.[53]

14. April 18, 2011, Harvard Drug Group agreed to pay $8,000,000 in civil penalties as part of settlement with DEA related to allegations that Harvard failed to have in place an effective system for identifying suspicious orders of controlled substances, violating the Controlled Substances Act.[54]

15. June 10, 2011, Order to Show Cause and Immediate Suspension Order served on Keysource Medical Inc. Keysource Medical distributed 48 million doses of oxycodone products to Florida Pharmacies.[55]

16. July 6, 2011, Order Denying Plantiff's (Keysource Medical) Motion for Temporary Restraining Order and for Preliminary Injunction.[56]

17. February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone.[57]

18. March 7, 2012, Memorandum of Opinion [Doc. 32] from the United States District Court for the District of Columbia, *Cardinal Health, Inc., vs. Eric H. Holder, Jr.*, Civil Action No. 12-185 (RBW), denying Cardinal's challenge of the DEA's Order to Show Cause and Immediate Suspension of Registration of Cardinal's Lakeland Distribution Center.[58]

19. April 5, 2012, A United States Attorney Office press release stated Keysource Medical agreed to pay a $320,000 fine for failing to guard against diversion of controlled

[53] United States Attorney's Office. (October 14, 2010) *CVS Admits Illegally Selling Pseudoephedrine to Criminals who made Methamphetamine, Agrees to Pay $77.6 Million to Resolve Government Investigation* [Press Release]. Available at https://www.justice.gov/archive/usao/cac/Pressroom/pr2010/148 html (last visited March 19, 2019).

[54] United States Drug Enforcement Administration. (April 18, 2011) *Michigan Based Pharmaceutical Wholesaler Harvard Drug Group to Pay $8,000,000 in Settlement* [Press Release]. Available at https://www.dea.gov/press-releases/2011/04/18/michigan-based-pharmaceutical-wholesaler-harvard-drug-group-pay-us (last viewed on March 19, 2019).

[55] United States Drug Enforcement Administration. (June 10, 2011) *Cincinnati Pharmaceutical Supplier's DEA License Suspended* [Press Release]. Available at https://www.dea.gov/press-releases/2011/06/10/cincinnati-pharmaceutical-suppliers-dea-license-suspended (last visited March 11, 2019).

[56] *Keysource Medical, Inc., v. Attorney General of the United States, et al.*, No. 1:2011cv00393, *Order Denying Plaintiff's Motion for Temporary Restraining Order and for Preliminary Injunction* [Doc. 22], available at https://law.justia.com/cases/federal/district-courts/ohio/ohsdce/1:2011cv00393/147299/22/ (last visited March 11, 2019).

[57] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

[58] Copy of Order available at https://www.govinfo.gov/content/pkg/USCOURTS-dcd-1_12-cv-00185/pdf/USCOURTS-dcd-1_12-cv-00185-0.pdf (last visited March 19, 2019).

substances. and states Keysource Medical agreed to voluntarily surrender their DEA registration in September 2011.[59]

20. May 14, 2012, Cardinal Health entered into an Administrative MOA with the DEA, which, among other things, stipulated that its compliance with the terms of the 2008 MOA were inadequate in certain respects and that its Lakeland, Florida Distribution Center's DEA registration would be suspended for two years.[60]

21. March 28, 2013, settlement was reached among the United States and the DEA and CVS Pharmacy, Inc and Oklahoma CVS Pharmacy, L.L.C., to resolve claims that CVS violated the CSA by: (1) filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; (2) entering and maintaining invalid DEA registration numbers on CVS dispensing records for certain prescriptions, which were at times provided to state prescription drug monitoring programs; and (3) entering and maintaining CVS dispensing records including prescription vial labels that identify a non-prescribing provider as the prescribing provider for certain prescriptions. CVS paid a fine of $11,000,000.00.[61]

22. In July, 2013, the DEA initiated a regulatory investigation at CVS Indiana. After the investigation and after the DEA had informally indicated its displeasure with what it found at CVS, Mark NiCastro, the CVS Indiana Director of Operations, sent correspondence to the DEA. In the correspondence, Mr. NiCastro attempted to explain to the DEA why the CVS Indiana distribution center had never reported a suspicious order and he wrote:

> "In your recent email, you asked for information concerning CVS store orders that have been stopped outside of Indiana. Across the chain, the CVS SOM process has stopped and cancelled orders. I have attached the dates and the offices to which we reported these orders. As we discussed during the DEA audit and during our recent phone call, it is important to remember that CVS is shipping only to its own stores, and there are additional due diligence processes in our pharmacy operations group which monitor the dispensing of prescriptions across the entire CVS chain to ensure appropriate dispensing by stores. This is a primary contributor to the limited number of suspicious orders identified through our distributor SOM process."[62]

[59] United States District Attorney's Office, Southern District of Ohio. (April 5, 2012) *Cincinnati Pharmaceutical Distributor to Pay $320,000 for Failing to Guard Against Diversion of Controlled Substances* [Press Release]. Available at https://www.justice.gov/archive/usao/ohs/news/04-05-12.html (last visited March 11, 2019).

[60] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

[61] CVS-MDLT1-000060822 – 000060829.

[62] *See* NiCastro Depo. at 204-207; Ex. 42.

23. July 17, 2013, Walgreens agreed to pay $80 Million in civil penalties related to allegations that Walgreens was filling numerous prescriptions that Walgreens employees knew, or should have known, were not issued for a legitimate medical purpose.[63]

24. June 19, 2014, In Regards to Masters Pharmaceutical the Administrative Law Judge issued a Recommended Decision in regards to the Order to Show Cause Hearing that occurred on February 24 through 28 and March 3 through 4, 2014. [64]

25. On September 2, 2014, settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The Settlement resolved claims against CVS for filling from April 1, 2012 to July 31, 2012, 153 prescriptions at eight different pharmacies, written by Dr. Pedro Garcia during a time period during which his Texas Department of Public Safety Controlled Substances registration was expired. CVS paid a $1,912,500 fine.[65]

26. On May 12, 2015, a settlement was reached among the United States and the DEA and CVS Health and all of its subsidiaries and affiliates. The Settlement resolved claims that CVS failed "to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 CF.R. §1306.64." The Settlement also covered CVS's "Florida Distribution Center[s] failure to maintain effective controls against the diversion of controlled substances into other than21 U.S.C. §823(e)" and failure to timely detect and report suspicious orders of controlled substances. CVS's conduct complained of is set forth in the February 2, 2012 Orders to Show Cause and Immediate Suspension Orders issued to CVS stores 219 and 5195. CVS paid a fine of $22,000,000.00.[66]

27. On July 24, 2015, a Settlement was reached among the United States and the DEA and CVS Health to resolves claims that from May 1, 2013 through July 30, 2014, CVS failed to keep complete and accurate records of Schedule II controlled substances at a CVS store in Massachusetts in violation of 21 U.S.C. § 827(a)(3) and 21 C.F.R. §§ 1304.11(e)(3)(i), 1304.21, and 1304.22; and that CVS failed to report a March 14, 2014 robbery to the DEA within one business day in violation 21 C.F.R. § 1301.76(b). CVS paid a $50,000 fine.[67]

28. On August 7, 2015, a Settlement was reached among the United States and the DEA and CVS Health. The Settlement resolved claims that between March 3, 2010 and August,

[63] United States Attorney's Office, Eastern District of New York. (July 17, 2013) *Eastern District U.S. Attorney's Office Participates in Record Settlement: Walgreens Agrees to Pay $80 Million in Civil Penalties Under the Controlled Substnaces Act* [Press Release]. Available at https://www.justice.gov/usao-edny/pr/eastern-district-us-attorney-s-office-participates-record-settlement-walgreens-agrees (last visited March 19, 2019).

[64] *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418-55,501 (Drug Enf't Admin. Sept. 15, 2015).

[65] CVS-MDLT1-00060907 – 000060914.

[66] CVS-MDLT1-000060796 – 000060804.

[67] CVS-MDLT1-000099702 –000099704.

2015 CVS stores in Rhode Island (1) filled prescriptions with invalid prescriber DEA number (knew or should have known in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.04); (2) filled prescriptions for Schedule III controlled substances written by psychiatric nurse practitioners who were not authorized under state law or by terms of their DEA registration to issue such prescriptions in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.03(a)(1); and (3) entering, creating, or maintaining CVS dispensing records in which the DEA registration numbers of non-prescribing practitioners, were substituted for the DEA registration numbers of prescribing practitioners in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1306.24. CVS paid a $450,000 fine.[68]

29. September 8, 2015, Masters Pharmaceutical – DEA Acting Administrator Chuck Rosenberg issued a Final Order revoking the DEA registration of Master Pharmaceutical Inc.[69]

30. On December 18, 2015, a Settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The Settlement was the result of a DEA Inspection that was performed after CVS reported the theft of over 40,000 dosages of controlled substances by two former employees from a Texas CVS pharmacy. The inspection that was started due to theft demonstrated that CVS again failed its CSA obligations. CVS paid a fine of $345,000.00.[70]

31. On December 31, 2015, the DEA issued a letter of admonishment for violations in distributing HCPs at the CVS Indiana distribution center. This DEA finding was the result of the July 2013 investigation. Before the admonishment, Agent Gillen of the DEA sent an email to Mr. Nicastro outlining that CVS Store No. 6880 ordered [redacted] dosage units of hydrocodone between January 1, 2012 and October of 2013. The pharmacy is located in Vincennes, IN with a population of approximately 18,000 people. Additionally, he indicated that Store No. 6757 ordered [redacted] of hydrocodone tablets for Columbus, IN, which has a population of 45,000. Agent Gillen then writes: "Both stores have purchased a large quantity of Hydrocodone given their population."[71]

32. On February 12, 2016, a Settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. In the Settlement, CVS acknowledged that between 2008 and 2012, "certain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA…" CVS paid a fine of $8,000,000.00.[72]

[68] CVS-MDLT1-000060847 – 000060855.

[69] *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418-55,501 (Drug Enf't Admin. Sept. 15, 2015).

[70] CVS-MDLT1-00060915-00060921.

[71] *See* CVS-MDLT1-00008014 – 00008015; CVS-MDLT1- 000076135.

[72] CVS-MDLT1-000060805-00060811.

33. June 30, 2016, CCS agreed to pay $3.5 Million to resolve allegations that 50 of its stores violated the Controlled Substances Act by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014.[73]

34. On October 20, 2016, a Settlement was reached among the United States and CVS Pharmacy, Inc. The Settlement resolved claims from an investigation that the DEA began in January 2016. The DEA investigated two CVS stores in Connecticut. Although the offending conduct occurred after CVS quit distributing HCPs, it is indicative of the overall pattern and practice of CVS. The Settlement resolves claims that CVS failed to keep paper Schedule III-V prescriptions either in a separate prescription file or readily retrievable from other prescription records, which allegedly violated 21 U.S.C. 827(b)(2)(A) and (B) and 21 C.F.R. 1304.04(h)(4) and failed to keep Schedule III-V purchase invoices on at least 31 occasions in separate or in a readily retrievable manner from all other records of the pharmacy, which allegedly violated 21 U.S.C. 827(b)(2)(A) AND (b) AND 21 C.F.R. 1304.04(h)(3). CVS paid a $600,000 fine.[74]

35. December 22, 2016, Consent Order entered into between the United States and Kinray, LLC, a subsidiary of Cardinal Health.[75]

36. December 23, 2016, Cardinal Health agreed to pay a $34 million civil penalty to the DEA to resolve allegations that it failed to report suspicious orders and meet its obligation under the CSA in Florida, Maryland, New York, and Washington.[76]

37. January 5, 2017, McKesson Corporation entered into an Administrative MOA with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.[77]

[73] United States District Attorney's Office, District of Massachusetts. (June 30, 2016) *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions* [Press Release]. Available at https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions (last visited March 19, 2019).

[74] CVS-MDLT1 000060830 – 000060838.

[75] *United States of America v. Kinray, LLC*, Case #16 Civ. 8767-RA. Available at https://www.justice.gov/usao-sdny/press-release/file/920806/download (last visited March 19, 2019).

[76] United States Attorney's Office, Middle District of Florida. (December 23, 2016) *United States Reaches $34 Million Settlement with Cardinal Health for Civil Penalties Under the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under (last visited March 19, 2019).

[77] United States Department of Justice. (January 17, 2017) *McKesson Agrees to Pay record $150 Million settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* [Press Release]. Available at

38. January 18, 2017, Walgreens agreed to pay $200,000 following an investigation by the Massachusetts Attorney General's Office found that Walgreens failed to track the opioid use of high-risk patients in the state's Medicaid program.[78]

39. March 9, 2017, Rite Aid paid $834,200 to the United States to settle claims that Rite Aid pharmacies in Los Angeles, California dispensed and/or recorded controlled substances using a medical practitioner's incorrect or invalid DEA registration number.[79]

40. June 30, 2017, the United States Court of Appeals for the District of Columbia Circuit published an opinion denying the Masters' petition of review and upholding the Final Order.[80]

41. On July 5, 2017, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The Settlement was the result of an investigation began by the DEA as a result of "an increase in the number of thefts and explained losses of Hydrocodone…" at numerous Eastern District of California CVS retail stores. The Settlement resolved claims for the following misconduct: 1) failure to "provide effective controls and procedures to guard against theft and diversion of controlled substances (*see* 21 C.F.R. §1301.71(a)) and failure to notify DEA of certain thefts or significant losses of controlled substances within one business day of the discovery (*see* 21 C.F.R. §1301.74(c)); 2) failure to maintain schedule 3-5 invoices (21 CFR §1304.04(a)); 3) failure to maintain Schedule 3-5 records separate from non-controlled substance records (21 CFR §1304.04 (h)(3)); 4) failure to conduct a Biennial Inventory on one specific day (21 CFR §1304.11(c)); 5) failure to maintain complete and accurate records (21 CFR §1304.21(a)); 6) failure to record the date of acquisition of controlled substances (21 CFR §1304.22(c), 1304.22(a)(2)(iv); 7) failure to record the amount received on Schedule 3-5 invoices (21 CFR §1304.22(c)); 8) failure to record the amount received and the date received on DEA 222 forms (21 CFR §1305.13(e)); 9) failure to maintain DEA-222 forms (21 CFR §1305. 17(a)); and 10) failure to maintain DEA-222 forms separate from other records (21 CFR §1305. 17(c)). CVS admitted that between April 30, 2011 and April 30, 2013 the retail stores violated their

https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (last visited March 19, 2019).

[78] Associated Press, "Walgreens to pay $200k, change opioid procedures," The Washington Times, January 19, 2017, available at https://www.washingtontimes.com/news/2017/jan/19/walgreens-to-pay-200k-change-opioid-procedures/) (last visited March 11, 2019).

[79] United States Attorney's Office, Central District of California. (March 9, 2017) *Rite Aid Corporation Pays $834,300 to Settle Allegations of Violating the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-cdca/pr/rite-aid-corporation-pays-834200-settle-allegations-violating-controlled-substances-act (last visited March 19, 2019).

[80] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

recordkeeping obligations, but it denied that the recordkeeping obligations caused any diversion. CVS paid a fine of $5,000,000.00.[81]

42. July 7, 2017, Department of Justice/DEA and Mallinckrodt entered into a Memorandum of Agreement to resolve allegations that if failed to maintain effective controls to prevent diversion and to detect and report suspicious orders.[82]

43. January 24, 2018, the U.S. Attorney's Office entered into settlement with Rite Aid for improper sales of the meth precursor pseudoephedrine.[83]

44. On June 15, 2018, a Settlement was reached among the United States and the DEA and CVS Health. The Settlement resolved claims that between February, 2013 and January, 2015, CVS failed to report to the DEA in writing, within one business day of discovery, thefts or significant losses of controlled substances, including hydrocodone, from certain Long Island CVS Pharmacy retail stores, as required by 21 C.F.R. §1301.76(b). CVS agreed to pay a $1,500,000.00 fine. (CVS-MDLT1-000060839 – 000060846).

45. On July 29, 2018, a Settlement was reached the among the United States and the DEA and CVS Pharmacy, Inc., to resolve claims related to a November 2013 inspection of a CVS Pharmacy in Calera, Alabama. The Settlement resolved claims that CVS violated the CSA, as a result of violations of : (1) 21 C.F.R. 1305.13(c) (requirement to record the amount received and/or the date received on DEA 222 forms); (2) 21 C.F.R. 1304.21(a) (requirement to maintain complete and accurate records); and (3) 21 C.F.R. 1304.21(a) and/or (d) (requirement to document the number of packages received or the date package received on Schedule III through V purchase invoices). CVS agreed to pay a $1,000,000 fine.[84]

46. August 21, 2018, CVS agreed to pay $1 Million to settle allegations that CVS stores in Alabama failed to keep adequate records in violation of the Controlled Substances Act.[85]

[81] CVS-MDLT1 000060856-000060871.

[82] Administrative Memorandum of Agreement between DEA and Mallinckrodt, plc and its subsidiary Mallinckrodt, LLC, dated July 7, 2017. Available at https://www.justice.gov/usao-edmi/press-release/file/986026/download (March 19, 2019).

[83] United States Attorney's Office, Southern District of West Virginia. (January 24, 2018) *U.S. Attorney's Office enters settlement with Rite Aid based on improper sales of meth precursor pseudoephedrine* [Press Release]. Available at https://www.justice.gov/usao-sdwv/pr/us-attorneys-office-enters-settlement-rite-aid-based-improper-sales-meth-precursor (last visited March 11, 2019).

[84] CVS-MDLT1-000060812 –000060821.

[85] United States Attorney's Office, Northern District of Alabama. (August 21, 2018) *CVS Pharmacy Pays $1 Million Penalty in Settlement with DOJ for Violations of the Controlled Substances* [Press Release]. Available at https://www.justice.gov/usao-ndal/pr/cvs-pharmacy-pays-1-million-penalty-settlement-doj-violations-controlled-substances-act (last visited March 19, 2019)

47. December 31, 2018, the DEA and the Rhode Island Attorney General announced $300,000 settlement with Rite Aid for filling prescriptions of Schedule III controlled substances in excess of statutory maximums.[86]

K. INDUSTRY GUIDELINES - HEALTHCARE DISTRIBUTION ALLIANCE

A large number of drug distributors and manufacturers are members of The Healthcare Distribution Alliance (HDA), a trade organization that provides industry information, provide guidance on best practices, industry standards, regulation/legal changes, and other related services.

A review of the website for The Healthcare Distribution Alliance (HDA) provided the following history of the organization.[87] The Western Wholesale Druggists' Association (WWDA) was formed on March 15, 1876 and consisted of 95 wholesale druggists. In 1882 the WWDA became the National Wholesale Druggists Association (NWDA) that was representing distribution companies as an advocate in the distribution industry.

In 2000 the NWDA organization was renamed Healthcare Distribution Management Association (HDMA). The website stated the organization changed reflected the "Association's vision of a progressively more efficient and effective distribution system." In 2016 the HDMA changed names to the Healthcare Distribution Alliance (HDA). The website states the following, "Now headquartered in Arlington, Virginia, HDA represents 36 distribution companies — national, regional and specialty — as well as more than 130 manufacturer and more than 50 service provider/international members, respectively. These members serve more than 200,000 licensed healthcare providers, delivering over 15 million lifesaving products to these outlets every day. But just as in 1876, HDA's mission has remained the same, which is to protect patient safety and access to medicines through safe and efficient distribution; advocate for standards, public policies and business processes that enhance the safety, efficiency and value of the healthcare supply chain; and, create and exchange industry knowledge and best practices."

NWDA 1984 Suspicious Order Monitoring Policy

A review of Cardinal Health discovery material revealed a thirty-eight page document from 1984 by NWDA which was a draft outline of a suspicious order monitoring system. The documents can be found in the Cardinal Health discovery material in a group of documents that begin with a cover page containing, "NWDA Suspicious Order Monitoring System" with this stamped information, "Received Jun 21 1993 by Folsom." [88]

[86] United States Drug Enforcement Administration. (December 31, 2018) *DEA and Attorney General Kilmartin announces $300,000 settlement with Rite Aid for filling prescriptions of Schedule III controlled substances in excess of statutory maximums* [Press Release]. Available at https://www.dea.gov/press-releases/2018/12/31/dea-and-attorney-general-kilmartin-announces-300000-settlement-rite-aid (last visited March 11, 2019).

[87] *See* https://www hda.org/ (last viewed on March 20, 2019).

[88] The group of documents described in this section can be found in the Cardinal Health discovery material with a Bates stamp range of CAH_MCL2804_01465723 to CAH_MCL2804_01465761.

The first seven pages of the document describes some of the elements of a suspicious order system. These seven pages do not contain a date indicating when the system was designed. There are two DEA letters in the documents that do identify a date which are letters from the DEA. These DEA letters provide comment and guidance to NWDA in regards to the suspicious order system. The first DEA letter was addressed to Mr. Ronald J. Streck, Vice President of Government Affairs (NWDA) and signed by G. Thomas Gitchel, Acting Chief Diversion Operations Section (DEA). The letter contained a stamped date of April 27, 1984, which details a meeting between the two on April 13, 1984. This letter stated the DEA reviewed a draft form of the suspicious order monitoring system. This DEA letter contained the following comment:

> The NWDA's draft format for a suspicious order monitoring system provides as excellent framework for distributor registrants to "…design and operate a system to disclose to the registrant suspicious orders of controlled substances." (21 CFR 1301.74(b).) However, I am compelled to note, as I have in our previous discussions, that any automated data compliance processing system may provide the means and mechanism for compliance when the data is carefully reviewed and monitored by the wholesaler. As previously discussed, an after-the-fact computer printout of the sales data does not relieve a registrant of its responsibility to report excessive or suspicious orders when discovered. I am enclosing a copy of your draft with my pen-and-ink changes."[89]

The second DEA letter was addressed to Mr. Ronald J. Streck, Vice President of Government Affairs (NWDA), signed by G. Thomas Gitchel, Acting Chief Diversion Operations Section (DEA) that was stamped with a date of May 14, 1984, which appeared to be a follow-up communication from the April 27, 1984 letter. This letter details that there was a NWDA meeting that was attended by DEA employee David Walkup. This DEA letter contained the following comment:

> I want to assure you that DEA fully supports NWDA's effort to introduce a uniform reporting system among its members. This system, as proposed, will meet the reporting requirements of 21 CFR 1301.74(b). However, I want to make it clear that the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders. DEA has interpreted "orders" to mean prior to a shipment.[90]

The background section of the system details it was created in co-operation with the DEA. Further, the document states that the DEA may be providing some variances and limits that would be incorporated into the suspicious order system.

On page 7 of the suspicious order system document is "Section IX" that contains the following statement: "Single orders of unusual size or deviation must be reported immediately. The submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of report these excessive or suspicious orders. DEA has interpreted "orders" to

[89] CAH_MDL2804_01465723, 01465732.

[90] CAH_MDL2804_01465723, 01465734.

mean prior to a shipment." This statement along with the letter from DEA is an important communication that identifies the DEA was requiring the suspicious order system to identify single orders of controlled substances that must report immediately prior to being shipped.

2008 Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Report Suspicious Orders and Preventing Diversion of Controlled Substances.

In 2008 the HDMA posted on their website industry compliance guidelines that were titled, "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances." In the introduction section of the document appeared this comment:

> At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support security of controlled substances they deliver to their customers. Due Diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them flor legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.[91]

On October 17, 2008, DEA Chief Counsel Attorney Wendy H. Goggins sent a written statement to HDMA President and CEO John M. Gray commending the HDMA for their efforts to assist their members in fulfilling the obligations regarding the Controlled Substance Act and corresponding regulations.[92]

The HDMA compliance guidelines document contains a general framework for a basic suspicious order monitoring system.[93] The document contains the following elements with accompanying suggested guidelines:

1. Know Your Customer Due Diligence
2. Monitoring for Suspicious Orders
3. Suspend/Stop an Order of Interest Shipment
4. Investigation of Orders of Interest
5. File Suspicious Order of Interest
6. Employees, Training and Standard Operating Procedures (SOPs)
7. Additional Recommendations
8. Glossary of Abbreviations

[91] February 10, 2012 Declaration of Joseph Rannazzisi, CAH_MDL_PRIORPROD_DEA12_00014479, 00014512.

[92] CAH_MDL_PRIORPROD_DEA12_00000825.

[93] CAH_MDL_PRIORPROD_DEA12_00000826.

Although there are several areas or concerns which might render a suspicious order monitoring system less effective, the guidance provided by HDMA does contain several key elements that are consistent with compliance with 21 C.F.R. Section 1301.71(a) and 1301.74(b). Some of the keys areas of the guidance are the following:

1. Recommending distributors conduct thorough due diligence investigations that are documented and retained is essential in establishing a customer and providing a history for any further compliance actions or investigations.[94]

2. Guidance for a distributor to develop an electronic suspicious order system as detailed in a standard operation procedure, although not required by regulation, demonstrates HDMA recognizes the manual review of orders for deviations in size, frequency, or pattern would render it ineffective.[95]

3. Separating customers by business activity or class of trade is an essential system element. Further enhancement for monitoring and setting averages would be to form subgroups by the size of the customer.[96]

4. Recommending of placing the controlled substances being monitored into groups or families provides a starting point for setting an average and monitoring. Only monitoring drug families and failing to evaluate the unusual order size, pattern, or frequency of any specific drug within a drug family has a much higher probability of failing to identify diversion of specific highly abused drugs.[97]

5. Thresholds are set as averages shipped to a customer's facility that are consistent with that class of customer. Threshold are recommended to calculated for single orders and average monthly orders per family, per customer, and class of trade. Thresholds should utilize the information obtained in the due diligence investigation. A sales history of a minimum of six months and maximum of 24 months is recommended. Thresholds for new customer accounts should be established at the lowest level indicated by the due diligence investigation. An important component is the periodic review of cumulative orders for the customer to evaluate purchasing trends. [98] Note: The use of a six-month average does not provide a sufficient purchase history for establishing accurate thresholds.

6. A distributor should consider allowing use of alternative criteria, outside of the suspicious order system, to be utilized to identify a suspicious order.[99]

7. On Page 9, Section III in the section titled, SUSPEND/STOP AN ORDER OF INTEREST SHIPMENT, there is clear guidance from HDMA of what action should be taken by

[94] CAH_MDL_PRIORPROD_DEA12_00000826, 00000829-00000832.

[95] CAH_MDL_PRIORPROD_DEA12_00000826, 00000832.

[96] CAH_MDL_PRIORPROD_DEA12_00000826, 00000833.

[97] *Id*.

[98] *Id*.

[99] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000834.

a distributor when an order exceeds a threshold which is contained in the following statement, "If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."[100]

8. Recommending if an order meets or exceeds a threshold the distributor examine the order further. The examination aids the distributor in deciding to either fill the order and ship or to continue to hold the order. This section also states, "Further examination will also aid in determining whether the and when to report the order to DEA under 21 C.F.R. Section 1301.74(b)."[101]

9. The following statement is made in regard to an order of interest, "The drug or drugs that cause an order to become an order of interest should not be shipped to the customer placing the order while the order is an order of interest."[102]

12. A customer interview should be conducted in regards to order. Any information provided by the customer should be verified and documented.[103]

13. All investigation conducted by the distributor should be "fully documented," and all records retained in an appropriate section. A critical element of guidance states the following, "The documentation should include a clear statement of the final conclusion of the investigation, including why the order investigated was (or was not) determined to be "suspicious." The statement should be signed and dated by the reviewer."[104]

15. Order determined to be "suspicious" should be reported immediately upon being so determined.[105]

18. The following guidance was provided for the content of the standard operating policy:

a. Describe how an initial review and investigation will be conducted;

b. Reflect the distributor's and its customers' business conditions;

c. Are sufficiently flexible to adjust the review/investigation to address the individual product/order/customer circumstances that are likely to occur;

[100] *Id*.

[101] *Id*.

[102] *Id*.

[103] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000835.

[104] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000836.

[105] *Id*.

d. Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";

e. Define a process for reporting to DEA under 21 C.F.R. Section 1301.74(b); and

f. Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.[106]

19. If a distributor concludes an order is suspicious after conducting an investigation it is recommended the distributor make a determination whether they will subject future orders from the same customer for the same drug product to more rigorous scrutiny and/or consider whether to cease filling all future orders of that drug product or all controlled substances.[107]

L. DEA CHEMICAL HANDLERS MANUAL

Cardinal Health (and others) have responded to discovery referencing the DEA's Chemical Handlers Manual and/or the 1998 Reno Report as "guidance" provided by the DEA regarding its suspicious order monitoring system for Schedule II and III controlled substances, including prescription opiates.[108] It is worth noting that these guidelines relate to "Listed Chemicals", rather than Schedule II and III controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. "Suspicious orders" of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of "extraordinary" size [based on a formula which generally multiples a monthly base weight average per base code by a multiplier (3x)]. Notably, the Chemical Handlers Manual also mandates:

> **When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making required reports, the transactions should not be completed until the customer is able to eliminate suspicions.**[109]

Relying upon a threshold of "extraordinary" size fails to detect orders of "unusual size" and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. Further, reliance on this threshold also does not detect orders of unusual pattern or frequency.

M. MAINTENANCE OF EFFECTIVE CONTROLS AGAINST DIVERSION OF CONTROLLED SUBSTANCES

Registrants engaged in actively distributing controlled substances should implement measures to comply with the legal and regulatory requirements. These measures should be documented as a standard operating policy for the company and be distributed to all relevant

[106] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000837.

[107] *Id*.

[108] *See, e.g.*, CAH_MDL_PRIORPROD_HOUSE_0002207; CAH_MDL_PRIORPROD_DEA07_01198690.

[109] CAH_MDL_PRIORPROD_DEA07_01198690, 01198713.

employees. These standardized policies should be designed by distributors and manufacturers to take the utmost precautions to prevent diversion by maintaining the "closed system" of distribution. Included below are some key components that one would expect to see an operational system designed to maintain effective controls against diversion.

- Registrants must have a comprehensive system in place and conduct an investigation on a customer who will be purchasing controlled substances. The following are some of the activities utilized to establish a new customer:
    - The review to establish a new customer and begin distribution of controlled substances is a critical 1st step to ensures a potential customer has a business plan consistent with compliance to the Controlled Substances Act. The review should confirm the information provided by the potential customer is accurate. One commonly used procedure by distributors is to utilize a customer questionnaire which asks a series of questions similar to the following:
        - Past history of DEA registration to determine compliance history
        - Check of state and local licensure compliance.
        - Compliance history with state medical/pharmacy board
        - Review the business plan to determine legitimacy of the customer
        - Identify any affiliation with pain management doctors
        - Review percentage of controlled substance business
        - Identify any other distributors providing control substances
        - Review the percentage of cash payments and insurance payments
        - Review of pharmacy utilization reports
        - On-site inspection of customer
        - Internet search to determine any negative information

- 21 C.F.R. §1301.74(b) requires all manufacturers and distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances. This regulation states that suspicious orders include orders of an unusual size, orders deviating substantially for a normal pattern, and orders or an unusual frequency. The regulation further states a registrant shall inform the local DEA Division Office of suspicious orders when discovered by the registrant. The regulation indicates it is the responsibility of the registrant to **design** and **operate** a suspicious order monitoring system. The design of a suspicious order system must clearly identify when the order is identified by the system. A system that establishes thresholds which are legitimate needs of a customer identified through a comprehensive "know your customer" should consider any orders exceeding that threshold as a suspicious order. The identified order should not be shipped and reported to the DEA. The subsequent shipping of that order would be after a due diligence investigation has determined the order is being shipped for legitimate use. A suspicious order system to be effective contains many components which should include, but not limited to, the following:
    - Customer Types – Customers should be placed in into customer types based on the business activity identified through the due diligence documentation.

- Scope of Practice – The system should monitor and/or restrict customers to only allow the ordering of controlled substances by schedule and type which have been identified as required for the legitimate medical needs of the practice.
- Customer Tiers/Groups – Customers who have been placed into customer types should be segregated by size in a minimum of three groups, based on the volume of their ordering history identified through the due diligence documentation.
- Drug Types – A suspicious order system to be effective should design drug types with more specificity that by drug group or drug code. Monitoring controlled substances only by the drug code or drug family is too broad and reduces the effectiveness of the system. Thresholds should also be designed for those controlled substances identified with a higher probability of being targeted for diversion.
- Thresholds – A distributor must identify the amount of controlled substances required by a customer for the legitimate operation of their business based on the registrant's knowledge of the customers business model, due diligence investigation, comparison of purchase amounts by other similar customers. Thresholds should be calculated based on the history of usage of customer for a period of at least 12 months.
- Population – The geographic distribution of controlled substances should be analyzed with relevant population information of available end users. The cumulative amount of controlled substances being distributed by a registrant to a geographic area or region should be monitored to insure it is consistent with legitimate population consumption. Customers who identify an activity of filling prescriptions from patients traveling from outside the area require a thorough due diligence type investigation including the review of dispensing records (without patient information) to confirm the legitimacy of the activity.
- Pattern of Orders – Reviewing orders to determine if there are patterns of ordering of controlled and non-controlled drugs with a comparison with relevant industry information on the most frequently prescribed drugs. If the ordering pattern deviates from established levels or what would be normal for another similarly situated customer this could indicate potential diversion.
- Pattern of Orders - Are controlled substances ordered in combinations of frequently abused drugs. As an example, purchasing the combination of oxycodone or hydrocodone products with Soma, Valium, and/or Xanax. The pattern of ordering of known highly abused controlled substances in comparison of other drugs can indicate diversion.
- Frequency of Orders – The frequency of orders for controlled substances increasing disproportionately for specific controlled substances that have been identified as being highly diverted.
- Geographic Distribution – The density of like businesses in geographic areas should be reviewed. Further, there should be a comparison of like customers in similarly situated geographic areas for deviation of volume and/or pattern of controlled substance orders. The system should identify large volume of controlled substances

consistently being received from a customer(s) in a state, county and city/township that does not have the appropriate customer base density.

- A robust and well-documented due diligence program is key for every compliance system to identify suspicious orders of controlled substances. As orders of controlled substances are identified due to factors such as size, pattern, or frequency, those orders may only be shipped if any suspicion is dispelled after adequate due diligence is conducted and it is determined that such orders are not likely to be diverted for illicit purposes. The elements and procedures involved in a due diligence compliance program for suspicious orders should be contained in a standard operation policy and should be readily available to all employees whose responsibilities touch on suspicious order monitoring. Characteristics of a robust due diligence should include the following:

    - An established procedure and criteria for setting threshold quantities.
    - The person or department who is responsible for approving threshold quantities is specifically identified.
    - A procedure for adjusting threshold quantities that requires thorough review and documentation.
    - Justification for the increase or decrease of thresholds documented by the registrant, and made after a review of factors such as the following:
        - Analysis of historical orders from the customer as well as any previous adjustments in thresholds and the justification previously provided
        - Analysis of the patient population serviced by the customer
        - Analysis of the physician population serviced by the customer
        - Analysis of the results of an adequate on-site customer review program
        - Analysis of other factors that could indicate to the registrant whether or not controlled substances are likely to be diverted for illicit purposes
    - Compliance review programs that have independent authority from other corporate entities/divisions to review thresholds as well as to approve or disapprove customers or threshold adjustments.
    - Sales role (if any) in the compliance review program must be appropriately managed.
    - On-site review includes the acquisition and review of utilization report.
    - Request for threshold changes necessitates an on-site review.
    - The person(s) is specifically identified who is responsible for reporting suspicious orders to the DEA.
    - Orders reported as suspicious that are subsequently shipped by the registrant have sufficient due diligence review being conducted and documented prior to distribution.

- The documentation of due diligence performed and the results thereof being retained
- Suspicious orders also being reported to states where applicable.
- Suspicious orders being reported as drug families and by individual drugs.
- Sufficient training and education for all involved in the distribution of controlled substances.

Almost as essential as the due diligence being conducted is that efforts made to dispel suspicions and the results thereof are adequately documented and retained. Thorough recordkeeping and documentation of the steps taken to justify flagged orders are necessary not only to explain why decisions were made in any particular instance, but also to inform future decisions regarding flagged orders. One important aspect of every due diligence review should always be an examination of the historical transactions of the customer who placed the flagged order. Such an examination is necessary to evaluate trends over time and to inform decisions about whether or not orders of controlled substances are likely to be diverted into illicit channels. For purposes of conducting a historical review of a customer when evaluating a flagged order, if prior due diligence investigations are not adequately documented and retained, they may as well have not occurred at all.

As explained above, the goal of suspicious order monitoring is to ensure that bulk orders of controlled substances are being shipped for legitimate purposes rather than being diverted for illicit purposes. A suspicious order monitoring system has a self-policing aspect with the twin aims of both stopping the shipment of orders at risk of diversion and investigating those who have placed orders that are identified as suspicious. Not shipping a suspicious order is only part of the equation. The other parts are investigating the buyer and the circumstances surrounding the order and, if necessary, reporting the suspicious order to the DEA. Any order that is suspicious requires action to dispel suspicion and confirm legitimacy. Otherwise the order should not ship. When a distributor neglects to dispel suspicion and ships anyway, the risk of diversion does not disappear when the order ships. For this reason, any future order or shipment to that particular pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

III. Identifying Suspicious Orders Distributed in CT1

I have described in this report the ways in which distributor and manufacturer defendants' inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed five suspicious order methodologies, some of which were

utilized by one or more of the defendants. These methodologies are identified in the McCann Report as "Maximum Monthly, Trailing 6 Month Threshold," "2x Trailing 12 Month average," "Extraordinary Order Method – 3x Trailing 12 Month Average," "Maximum 8,000 Dosage Units Monthly," and "Maximum Daily Dosage Units." The purpose of each system was to identify suspicious orders that should not be shipped unless the distributors' due diligence eliminated the suspicion of diversion. Each method would have identified a significant volume of orders of opiates as shown in the tables below.[110]

A. Methodology: Maximum Monthly, Trailing 6 Month Threshold

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug (p. 46)	[redacted]	
Cardinal (p. 91)		
McKesson Corporation (p. 136)		
CVS (p. 181)		
Walgreens (p. 236)		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug (p. 676)	[redacted]	
Cardinal (p. 721)		
McKesson Corporation (p. 766)		
CVS (p. 811)		
Walgreens (p. 236)		

[110] I utilized these Defendants: Cardinal Health, AmerisourceBergen Drug, McKesson, Walgreens, and CVS as they constitute a significant majority of the opioid pills delivered into CT1 according to the data described in the Expert Report of Craig J. McCann, Ph.D., CFA, App. 9, pp. 3775 and 3845.

B. Methodology: 2x Trailing 12 Month Average

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[111]	[redacted]	
Cardinal[112]		
McKesson Corporation[113]		
CVS[114]		
Walgreens[115]		

Summit County: 1996-2018

Distributor
AmerisourceBergen Drug[116]
Cardinal[117]
McKesson Corporation[118]
CVS[119]
Walgreens[120]

[111] *Id*. at 55.

[112] *Id*. at 100.

[113] *Id*. at 145.

[114] *Id*. at 190.

[115] *Id*. at 235.

[116] *Id*. at 685.

[117] *Id*. at 730.

[118] *Id*. at 775.

[119] *Id*. at 20.

[120] *Id*. at 865.

C. Methodology: Extraordinary Order Method - 3x Trailing 12 Month Average

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[121]	[redacted]	
Cardinal[122]		
McKesson Corporation[123]		
CVS[124]		
Walgreens[125]		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[126]	[redacted]	
Cardinal[127]		
McKesson Corporation[128]		
CVS[129]		

[121] *Id*. at 64.

[122] *Id*. at 109.

[123] *Id*. at 154.

[124] *Id*. at 199.

[125] *Id*. at 244.

[126] *Id*. at 694.

[127] *Id*. at 739.

[128] *Id*. at 784.

[129] *Id*. at 829.

Walgreens[130]	[redacted]

D. Methodology: Maximum 8,000 Dosage Units Monthly

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[131]	[redacted]	
Cardinal[132]		
McKesson Corporation[133]		
CVS[134]		
Walgreens[135]		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[136]	[redacted]	
Cardinal[137]		
McKesson Corporation[138]		

[130] *Id*. at 874.

[131] *Id*. at 73.

[132] *Id*. at 118.

[133] *Id*. at 163.

[134] *Id*. at 208.

[135] *Id*. at 253.

[136] *Id*. at 703.

[137] *Id*. at 748.

[138] *Id*. at 793.

CVS[139]	[redacted]
Walgreens[140]	

E. Methodology: Maximum Daily Dosage Units

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[141]	[redacted]	
Cardinal[142]		
McKesson Corporation[143]		
CVS[144]		
Walgreens[145]		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[146]	[redacted]	
Cardinal[147]		

[139] *Id*. at 838.

[140] *Id*. at 883.

[141] *Id*. at 82.

[142] *Id*. at 127.

[143] *Id*. at 172.

[144] *Id*. at 217.

[145] *Id*. at 262.

[146] *Id*. at 712.

[147] *Id*. at 757.

McKesson Corporation[148]	[redacted]
CVS[149]	
Walgreens[150]	

I have been asked to identify the number of opioid pills that entered Cuyahoga and Summit Counties unlawfully. This is an impossible task due to the defendants' failure to comply with their Federal statutory and regulatory requirements.[151] However, it is my opinion to a reasonable degree of professional certainty that applying the test set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.[152] *See* Methodology A above. Pursuant to *Masters,* "as a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence" *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 216 (D.C. Cir. 2017). I say this understanding that this litigation will be advanced by selecting a methodology quantifying a volume of pills that entered CT1 jurisdictions unlawfully and providing this data to an economist to measure the harm caused by this volume.

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants' failures to comply with the requirements of the Controlled Substances Act. It is further my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in CT1 jurisdictions.

IV. REGISTRANT SUSPICIOUS ORDER MONITORING SYSTEMS (SOMS)

I have been asked to review the documents produced in this litigation to determine whether the distributors complied with the statutory and regulatory duties outlined above. In this process I have reviewed numerous documents and depositions for each of the enumerated Defendants. Based on my review it is my opinion to a reasonable degree of professional certainty that each of the distributors failed to comply with their statutory and regulatory duty to maintain effective controls to prevent diversion and to design and operate a system to identify and report suspicious orders.

[148] *Id*. at 802.

[149] *Id*. at 847.

[150] *Id*. at 892.

[151] This includes, but is not limited to, the requirement of the defendants to maintain effective controls against diversion, the reporting requirement, and the not shipping requirement. The detail of some of these failures is set out more completely below in the distributor and manufacturer specific sections of this report.

[152] This approach does not take into consideration unusual pattern or frequency.

and 2017.[683] Further, as of 2018, Henry Schein may still approve a pended order of interest without contacting the customer, relying only on a due diligence letter from a prior pended order of interest with that same customer.[684] Currently, Henry Schein does not perform any criminal background checks or medical/dental board disciplinary checks on any of their doctor customers as part of their due diligence inquiry.[685]

V. MANUFACTURERS

It is my expert opinion that manufacturers of opioids, as DEA registrants, have the same duties as wholesalers to maintain effective controls to prevent diversion of controlled substances into other than legitimate medical, scientific, and industrial channels.[686] The fact that manufacturers hold a different position in the supply chain, and have different sources of information and knowledge, does not change the underlying duty.

Specifically, manufacturers of opioids must, among other regulatory requirements, maintain effective controls to prevent diversion, which include, but are not limited to, the following elements:

1. Design and operate suspicious order monitoring systems that operate effectively to identify, report, and not ship suspicious orders.[687]

2. Make use of all relevant prescribing and transactional data and information they obtain in the course of their business activity to identify and prevent diversion and identify suspicious orders.

Manufacturers must ensure that their direct customers—for the most part, distributors—have sufficient controls in place to prevent diversion of controlled substances. Manufacturers, initially and then periodically, must verify that their customers maintain effective controls to prevent diversion.

Manufacturers must review the orders that distributors place with them to detect suspicious orders, which include, but are not limited to, orders of an unusual size or frequency or that deviate from the normal pattern.[688] Upon discovery, manufacturers must report and not ship these orders.

[683] *See* Abreu Dep. at 310:15-314:15; *also see* Peacock Dep. at 69:22-71:9; 129:11-130:24.

[684] *See* Abreu Dep. at 255:6-256:13; HSI-MDL-00404203-209.

[685] *See* Peacock Dep. at 132:22-133:1; *also see* Steffanie-Oak Dep. at 105:1-106:23.

[686] 21 USC § 823 (b)(1); 21 CFR § 1301.74(b).

[687] 21 CFR 1301.74(b).

[688] *See Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 221 (D.C. Cir. 2017) ("Section 1301.74(b) defines suspicious orders as "includ[ing]" orders of an unusual size, pattern, or frequency, and it is well established that the word "include" often precedes a list of "illustrative" examples, rather than an exclusive list of

These orders may not be shipped unless the manufacturer conducts and documents its own due diligence investigation of these orders and dispels the basis for its suspicion. That does not mean simply relying on the representation by a distributor that there is a reasonable basis for the order. Actual (and documented) investigations to verify the information must be conducted by the manufacturer to confirm that the order is not diverted into other than legitimate medical, scientific, and industrial channels.

I am aware that some manufacturers have some data on doctors' prescribing of opioids, which manufacturers purchase from companies like IQVIA (formerly IMS). It is my understanding that manufacturers obtain this data in order to target and monitor their marketing efforts. This data also allows manufacturers to identify prescribers who prescribe opioids in volumes, types, doses, and combinations, or with frequencies that are indicative of diversion.

I am also aware that manufacturers also have access to chargeback or fee for services data (collectively, "chargeback data"), which is provided by distributors. This data provides transaction information allowing manufacturers to determine who purchased its drugs, in what volumes, and in which doses. Using chargeback data, manufacturers could identify pharmacies or other customers whose orders of opioids were of an unusual size, frequency, or pattern, or suspicious in other ways that are indicative of diversion. Manufacturers could also determine whether a pharmacy is obtaining opioids through multiple distributors, a red flag of diversion. Manufacturers could also use chargeback data to monitor the geographic distribution of their drugs in order to assess whether their drugs are being supplied to hotspots of opioid abuse or in volumes that are disproportionate to a legitimate market in an area. Based on the documents I reviewed, including documents from Purdue Pharma, it is clear that manufacturers could and did identify the largest prescribers and dispensers of their drugs.

Using relevant data acquired by a manufacturer for compliance purposes is part of maintaining effective controls to prevent diversion. This obligation was acknowledged by Mallinckrodt in the Memorandum of Agreement Mallinckrodt entered with the United States in 2017.[689] Mallinckrodt confirmed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b)" and "utilize all available transaction information to identify suspicious orders of any Mallinckrodt product."[690] Mallinckrodt agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[691] Mallinckrodt also acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their

indicia of an identified wrong. [internal citations omitted]. […] Reading section 1301.74(b)'s listed characteristics as exemplary rather than exhaustive, DEA reasonably concluded that other indicia may also raise suspicions about an order for controlled substances.")

689 Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 5 (July 10, 2017), *available at* https://www.justice.gov/usao-edmi/press-release/file/986026/download.

690 *Id.* at 4

691 *Id.*

direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." As part of the resolution, Mallinckrodt agreed that it could and would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[692]

Thus, to comply with the law, manufacturers that have prescribing and chargeback data are obligated to incorporate that data into their compliance programs to meet their duties to maintain effective controls to prevent diversion. Put another way, manufacturers "know what they know" and must put that knowledge to use when they know it to prevent diversion. Manufacturers must analyze this data using metrics or methods that are reasonably designed to identify suspicious orders and that are not so high that they fail to detect suspicious orders. As DEA had pointed out: "[r]egistrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders."[693] Changing these metrics or methods in a suspicious order system to avoid flagging too many suspicious orders is not an effective control on diversion. These metrics must look specifically at drugs (or National Drug Codes, known as "NDCs") that are known targets of diversion, and not just at drug families. In addition, manufacturers must conduct and document a due diligence investigation to ensure that the drugs are not being diverted.

Manufacturers' sales representatives provide additional visibility into the manufacturers' downstream customers purchasing their products. These sales representatives have on-site interaction with doctors' offices and pharmacies through regular visits. These visits allow the manufacturers the ability to observe red flags of diversion – long lines, potentially inappropriate customers, cash payments, and other signs of abuse that would have alerted them to potential diversion of opioids. These observations of red flags also must be integrated into manufacturers' compliance programs.

An example of sales representatives ignoring signs of diversion is illustrated in the case of Dr. Adolph Harper, Jr., a physician in Akron, Ohio. Although his specialty was obstetrics and gynecology, Harper prescribed a substantial volume of opioids.

On October 20, 2014, Harper pleaded guilty to one count of conspiracy to traffic drugs, four counts of health care fraud and sixteen counts of drug trafficking. He was subsequently sentenced to ten years imprisonment. The Department of Justice's news release regarding Harper's sentencing indicated that Harper distributed "hundreds of thousands of doses of prescription medications – including OxyContin, Percocet, Roxicet, Opana and others – from his

692 2017 Mallinckrodt MOA at 5.

693 *See* MNK-T1_7146630, Ratliff Ex. 8 (letter from Deputy Assistant Administrator Joseph Rannazzisi to Mallinckrodt (Dec. 27, 2007)).

medical offices in Akron between 2009 and 2012."[694] The sentencing memorandum indicates that at least eight of Adolph Harper's patients died as a result of drug overdoses.[695]

In the sentencing memorandum, prosecutors described an office environment that should have alerted any sales representative who visited Harper's office: "The atmosphere of Harper's office, like his prescribing practices, was also more akin to street-level drug trafficking operation rather than a medical office. Harper's customers often waited for hours to see Harper, and many of these customers exhibited behavior consistent with drug abuse. Witnesses reported seeing customers passed out in the hallway and office while waiting to see Harper, or vomiting or urinating on the floor in the waiting room. Customers were also combative and aggressive with Harper's staff members if there was any delay in receiving their drugs."[696]

I reviewed a declaration from Ramona Harrison, who was a receptionist at Harper's office from 2010 through January 2012.[697] Harrison said that most of Harper's patients appeared to be drug addicts. They often looked disheveled and acted like they were "high" on drugs. Harper's waiting room was usually full, with some people needing to stand because there were not enough seats. Many patients "nodded off' while they were waiting to see the doctors. Others were belligerent to the staff or argued with other patients in the waiting room. Harrison noted that some patients even urinated on themselves and some patients periodically vomited in the water fountain.[698]

I am informed that, from 1994 through 2005, Harper was called upon at least 109 times by Purdue sales representatives.[699] Purdue's last recorded call to Harper's office occurred on September 14, 2005.[700] Two months later, on November 17, 2005, a Purdue email stated, "Purdue determined that the sales representative should cease sales calls on Dr. Harper."[701] I have not seen any documentation that Purdue reported Harper to state or federal authorities.

Based on documents I reviewed, Endo, Cephalon, and Janssen also visited Harper and held programs that he attended, and he was marketed Opana, Actiq, Nucynta, and Kadian.[702] Harper was eventually removed from Endo's call plan according to an April 20, 2012 document, with the

694 "Akron Doctor Sentenced to 10 Years in Prison For Illegally Prescribing Painkillers, Even After Patients Died," U.S. Dep't of Justice Press Release (Feb. 13, 2015) https://www.justice.gov/usao-ndoh/pr/akron-doctor-sentenced-10-years-prison-illegally-prescribing-painkillers-even-after.

695 PLTF_2804-000013676 at 5.

696 *Id* at 4.

697 PLTF_2804_000004562.

698 *Id.*

699 PPLPMDL0030005334.

700 *Id.*

701 PPLPMDL0030005327.

702 ENDO-OPIOID_MDL-00673563; TEVA_MDL_A_02416207; JAN-OH-00006800.

explanation: "License is being investigated and has made local news due to questionable actions."[703] This indicated that the removal was based on media reports, as opposed to feedback from Endo representatives in the field. I am also informed that, according to DEA ARCOS data, between 2006 and 2009, Harper directly purchased opioids directly from Henry Schein.[704]

According to prosecutors' sentencing memorandum, several Akron-area pharmacies began refusing to fill Adolph Harper's prescriptions.[705] Rite Aid store 3182 in Akron continued to fill Harper's prescriptions and requested an increase in its oxycodone thresholds from McKesson after the store received an influx of Harper's patients turned away by another Rite Aid branch.[706] Emails obtained from McKesson disclosed that in September and October 2011, Rite Aid store 3182 requested that McKesson increase its threshold on oxycodone by 15 percent because of "increased activity from a local pain mgmt. doctor," Adolph Harper.[707] It appears McKesson approved the first request, but denied the October 2011 the additional increase. Oriente wrote that Harper "may be an issue that you may want to do additional due diligence on. He is an Ob/Gyn not a Pain Management Specialist."[708] Oriente included complaints about Harper from individuals who had posted to the website Vitals.com:

- September 29, 2011: "No one is filling his prescriptions! … some of us are very sick and not just drug addicts!" [709]
- July 15, 2011: "YOUNG PEOPLE ARE DYING BECAUSE THIS MAN WILL GIVE PAIN PILLS AND XANAX TO ANYONE! PLEASE SOMEONE STEP IN BEFORE ANOTHER LIFE IS LOST."[710]
- July 6, 2011: "gives my daughter any pills she wants as long as he can be a pervert once a month and check her, in trouble with drug board, he will get you addicted to any pills, he is not a doctor he is a drug dealer with his own daughters as accessories."[711]

A Director of Loss Prevention for Rite Aid responded, "I agree, we ran a report and checked his DEA number and saw the same thing. We have the [Pharmacy District Manager] reviewing a checklist to visit the clinic. No increases at this time."[712]

703 ENDO-OPIOID_MDL-02816744 & END00746489

704 HIS-MDL-00001612; HIS-MDL-00648726.

705 PLTF_2804_000013676 at 4.

706 MCKMDL00632908; MCKMDL00626683; PLTF_2804_000013676 at 4.

707 MCKMDL00632908 & MCKMDL00626683

708 MCKMDL00627631.

709 *Id.*

710 *Id.*

711 *Id.*

712 MCKMDL00634992.

It is my expert opinion that:

1. Sales representatives who visited Dr. Harper should have been aware of and reported the signs of diversion at his practice.

2. A distributor who directly supplied opioids to Dr. Harper should have visited his practice and observed and reported signs of diversion.

3. The increase in volume associated with Dr. Harper's prescribing should have—and did—alert distributors and pharmacies to Dr. Harper's suspicious prescribing, and those entities should have reported Dr. Harper.

Manufacturers that knew or should have known of suspected diversion of their products by prescribers and/or pharmacies through relevant transaction data, sales representatives' visits, or any other means are required to take action to maintain effective controls to prevent diversion. Manufacturers should have investigated whether the suspected diversion was the result of deficiencies in their distributors' overall compliance program, including the suspicious order monitoring system that supplied their products to the prescribers and/or pharmacies. The obligation for taking action exists when the diversion was or should have been discovered, even if that was after the orders were shipped to those customers, to prevent diversion and protect the public interest. To the extent that a manufacturer was aware of potential diversion, whether by a distributor, prescriber, or pharmacy, the manufacturer should have reported the relevant conduct to the DEA. In addition, manufacturers that continued to distribute their products with reason to believe those products were being diverted demonstrated a failure to maintain effective controls against the prevention of diversion.

In sum, whatever specific methodology a manufacturer used (or failed to use) to implement effective controls to prevent diversion, to design and operate a system to disclose suspicious orders, all manufacturers had the obligation to: (1) evaluate all relevant data and information available to them to prevent and report diversion; (2) identify, report, and stop shipment of suspicious orders of opioids; and (3) if shipping those suspicious orders, conduct sufficient due diligence to ensure that those orders are not being diverted into other than legitimate medical, scientific, and industrial channels. Manufacturers that do not have effective systems to carry out these obligations, or do not consistently or sufficiently implement these systems, failed to comply with the law.

Based (a) on my education, training and experience, (b) the law, regulation and practices in the area of CSA enforcement, and (c) on my review of document and testimony provided in this case (MDL 2804), I am of the opinion to a reasonable degree of professional certainty:

1. Manufacturers with relevant transaction data including the distribution, dispensing, and prescribing of their opioids by their direct and downstream customers had an obligation to utilize that data in their compliance programs. The failure to integrate that data into their

compliance programs was a failure to implement and/or maintain effective controls to prevent diversion.

2. Suspicious order monitoring programs that use rigid multipliers of two or three times the average purchase amount to trigger or disclose a suspicious order do not effectively identify suspicious orders.

3. Suspicious order monitoring programs that are designed to only evaluate orders by drug code or by drug family and fail to assess specific NDCs that are known targets of diversion mask potential diversion and are ineffective.

4. Manufactures that identify suspicious orders and ship those order must conduct and document a due diligence investigation to ensure those drugs are not being diverted into other than medical, scientific and industrial channels or they are failing to maintain effective controls to prevent diversion.

5. Manufacturers that adjust their programs for identifying suspicious orders in order to reduce the number of orders that were identified as suspicious, without regard to whether those orders were suspicious or not, fail to maintain effective controls to prevent diversion.

Set out below, based on my review of documents produced and testimony given by defendants in this litigation, are examples of systemic failures of compliance in the various manufacturers' obligation to maintain effective controls and suspicious order monitoring programs.

A. ALLERGAN

Based on the evidence I have reviewed in this case, Allergan and its predecessor entities failed to maintain effective controls to prevent diversion, failed to design and operate adequate suspicious order monitoring systems, and failed to take reasonable steps to prevent the Allergan entities' products from being diverted. This conclusion is based on my review of the evidence including the following facts:

1. In 2012, Watson Pharmaceuticals, Inc. purchased Actavis, Inc., and the combined company took the "Actavis" name.[713] In March 2015, Actavis purchased Allergan, Inc. and, renamed itself again to "Allergan."[714]

[713] https://www.Allergan.com/news/news/thomson-reuters/watson-pharmaceuticals-inc-is-now-actavis-inc The Allergan Defendants include Allergan plc, Actavis, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis Pharma, Inc., Actavis LLC, as well as other related subsidiaries.

[714] https://www.Allergan.com/news/news/thomson-reuters/actavis-plc-is-now-Allergan-plc. Through a 2013 acquisition, the company had become a "plc" and moved its headquarters to Ireland to take advantage of "a favorable tax structure" but kept its executive headquarters in New Jersey, USA. *See* https://www.Allergan.com/news/news/thomson-reuters/actavis-to-acquire-warner-chilcott-to-create-premi

inventory component. Like the pre-merger Actavis system, it only looked for orders of unusual size and not for frequency and/or pattern in real time. The rigid formula used did not satisfy DEA requirements to detect and investigate suspicious orders. The automated portion of the system did not utilize any downstream customer information available, did not differentiate among NDC codes for drugs with a higher risk of diversion, and only manually stopped orders from shipping. The companies' failure to identify suspicious orders was known among their employees. It was these same employees that cut or reduced orders in order to avoid filling a suspicious order. The SOM was not an effective control and the Watson and Actavis employees recognized as much. Yet the system remained in place until 2016, and was not replaced. Now, Allergan asserts that as a "virtual manufacturer" that outsources its manufacturing, transport and delivery systems, it is no longer a DEA registrant with regard to Kadian and Norco, and need not have a suspicious order monitoring system at all.[756] In my expert opinion, there is no category of "virtual" manufacturers, and Allergan cannot delegate its duties to prevent diversion.

B. JANSSEN

Based on the evidence I have reviewed in this case, Janssen failed to maintain effective controls to prevent diversion by failing to implement adequate compliance to prevent its products from being diverted. This conclusion is based on the following facts, as established by the evidence in this case and as elaborated on in more detail throughout this section:

1. Janssen's SOM program began in 2006 with its first Standard Operating Procedure for its SOM policy, in which Janssen wrote that a "potentially suspicious or excessive" controlled substance order can be defined as an order "that exceed[s] the permitted quantity by 3 times the normal mean demand" over a 52-week period.[757]

2. In 2013, Janssen modified its definition of suspicious order, stating, "A potentially suspicious or excessive controlled substance order can be defined as an order that exceeds the minimum order quantity requirements, and is above 3x's (300% of) the calculated, 12 month, per weekly order average."[758] Janssen maintained its same suspicious order algorithm from 2006 through at least the date of the deposition of Janssen's Controlled Substances Compliance Director, Michele Dempsey, on March 8, 2019.[759]

3. From 2005 through at least 2018, Janssen has never reported a suspicious order to the DEA.[760]

[756] *See e.g.*, Acquired_Actavis_01843335 (discussing regulation of entities that refer to themselves as "virtual manufacturers").

[757] *See* JAN-MS-03741170.

[758] *See* JAN-MS-03124101 (Dempsey Deposition Exhibit 37).

[759] *See* Dempsey Deposition at 471:23-472:18.

[760] *See* Dempsey Deposition at 487:2-488:18; *see also* JAN-MS-05444748 at 761 (Dempsey Deposition Exhibit 26 (Janssen's SOM Audit Report, stating, "It appears that the JOM SOM has not reported a suspicious order for controlled substances as suspicious during its entire time in operation.").

4. Janssen only monitored for orders of unusual size and failed to ever monitor for frequency and/or pattern in real-time.[761]

5. Beginning in 2005, Janssen received chargeback data that would have provided visibility into the orders of its opioids by downstream customers.[762]

6. Further, since at least 2011, Janssen's "SCG Trade Group" and its "marketing teams" were using 852 data (wholesalers' inventory and total sales out to their customers) and un-blinded 867 data ("wholesalers total sales out to their customers broken out by outlet, *i.e.*, Retail Pharmacies, Hospitals, Long Term Care, Clinics, etc. Last Points-of-Care in the Supply Chain where product is shipped prior to delivering to the patients"), as well as chargeback data to gain insights into purchasing behavior of individual pharmacies and other customers to resolve demand issues and help build demand strategies.[763] According to Janssen's documents, this information was used by sales and marketing to spot high prescribers and to ensure that wholesalers were stocking targeted pharmacies with Janssen's opioids.[764] Janssen also was buying third party data from Integrichain and ValueTrak.[765]

7. Janssen's Director of Controlled Substances Compliance, Michele Dempsey was asked whether her compliance group was getting stocking data while looking at suspicious order monitoring in 2012. The answer was, "no, we were not."[766] When asked if it might have been useful to see which pharmacies were stocking at a higher volume than others in a given zip code, Ms. Dempsey replied, "No."[767]

8. Janssen never incorporated any of the relevant transactional sales data that could assist in disclosing diversion into its real-time SOM system, including, IQVIA, chargeback data, sales representatives' tips, or even the Integrichain and ValueTrak data that its Trade Analytics team was using in order to sell its opioid products and track stocking at the pharmacy level.

9. In 2012, Janssen Ortho-McNeil's ("JOM") "Customer Service" team was required to use ValueTrak data after a distributor customer's order was flagged as potentially suspicious

761 *See* Dempsey Deposition at 433:21-455:13.

762 *See* JAN-MS-01117436 at slide 3 ("In 2005, wholesalers began sending us information on their shipments to qualify for Distributor Performance Agreement (DPA). Key information we receive: . . . 844/849 – Chargeback data which identifies how much a vendor qualifies for rebates.").

763 *See* JAN-MS-01117436 at slide 3.

764 *See* JAN-MS-00454956.

765 *See* JAN-MS-01117436.

766 *See* Dempsey Deposition at 106:1-8; 111:14-18.

767 *See* Dempsey Deposition at 114:11-19.

or excessive, and after receive a reason for the increase in demand, only "to show the [distributor] customer's inventory and compare that inventory to the demand of the increase."[768]

10. Ms. Dempsey testified that Janssen only utilized 852 and 867 data from the wholesaler in its order monitoring program, "as needed."[769] However, Ms. Dempsey testified that, in 2017, when she was aware that another division within Janssen was getting third party 852 and 867 sales data, "I don't know if prior to 2017 [the third party data] did include Duragesic and Nucynta. But at the time that I was – I learned of this [third party data], Duragesic was not included, and Nucynta was no longer a product."[770] In my expert opinion, consistent utilization of this third party data to monitor sales of Janssen's Duragesic and Nucynta for orders that should have been flagged for review based upon unusual size, frequency or pattern, certainly was necessary to identify potential diversion when evaluating potentially suspicious orders and should have been used for that purpose.

11. Additionally, through purchases of data from ValueTrak,[771] Janssen stated that "we can now identify the most valuable individual pharmacies in the marketplace."[772] Ms. Dempsey further testified that she was unaware that Janssen was purchasing such third party data until 2017.[773] Ms. Dempsey also testified that she was unaware that Janssen had the "ability to unblind the sales it was making to wholesalers to obtain visibility of [Janssen's] inventory at individual retail stores" until "2017."[774] This data enabled Janssen to know the end customers of its distributors. Janssen was using this information, in addition to monitoring pharmacy inventory, to track the "hot spot markets prescribers writing the higher strengths so [Janssen] can provide that data to the JOM Planners and Wholesaler Buyers."[775] However, Janssen was not incorporating the third party data into its real-time order monitoring platform.[776]

768 *See* JAN-MS-03124101 at JAN-MS-03124105, section 7.1.6 (Dempsey Deposition Exhibit 37).

769 Ms. Dempsey testified, ". . . when an order, a controlled substance order, goes through the order monitoring program, if it is deemed to be questionable, customer service planning is involved in reaching out to the customer to understand why it is not a typical order. And this data is used to -- in some cases, as justification to show that downstream inventory is low and it required additional information -- this order was justified for release." *See* Dempsey Deposition at 123:11-124; *see also* 122:16-123:9 and 132:18-134:11.

770 *See* Dempsey Deposition at 104:3-16.

771 *See* JAN-MS-00454956; JAN-MS-01117436.

772 *See* JAN-MS-01117436 (844-849 – "Stocking Tool Territory Level: For the first time, our sales reps know which pharmacies have purchased, and which high decile pharmacies have not purchased our products." *Id.* at slide 14 (depicting how Janssen was tracking Nucynta down to the specific pharmacies, such as specific CVS, Walgreens and Wal-Mart locations).

773 *See* Dempsey Deposition at 340:6 – 343:20.

774 *See* Dempsey Deposition at 98:15-99:16.

775 *See* JAN-MS-00454956.

776 *See* Dempsey Deposition at 133:2-134:12.

12. Janssen's SOPs did not cover pharmacies or prescribers. Michele Dempsey testified that she was unaware that Janssen's sales group was doing trend analysis on its higher prescribers of Nucynta and Duragesic. When pressed on whether she would have wanted to know the prescriber data trends in her role, she replied, "No."[777] As above, I believe Janssen should have been using its data and analysis on prescribers to inform its suspicious order monitoring program relative to its due diligence obligations.

Without restating every finding laid out above, I conclude that Janssen's real time order monitoring program only looked for orders of unusual size and not for frequency and/or pattern. The rigid formula used did not satisfy DEA requirements to detect and investigate suspicious orders, and was set high to effectively identify diversion or suspicious orders. Further, Janssen's Controlled Substances Compliance Director, Ms. Dempsey, confirmed that downstream data was only utilized in "some cases as justification to show that downstream inventory is low. . ." and additionally testified that "during our monthly compliance reviews [which started in 2013] it was presented as a data source that could be used, potentially, to help investigate questionable orders,"[778] but did not know as of 2017 whether the third party included information concerning Nucynta and Duragesic. Further, Janssen's real time order monitoring system did not utilize any downstream customer information available, and did not differentiate among NDC codes for drugs with a higher risk of diversion. The SOM design was not effective in identifying suspicious orders.

C. MALLINCKRODT

Based on the evidence I have reviewed in this case, Mallinckrodt did not maintain effective controls to prevent diversion, failed to design and operate an adequate suspicious order system , and failed to take reasonable steps to prevent its products from being diverted. This conclusion is based on the following facts, as established by the evidence in this case and as elaborated on in more detail throughout this section:

1. The record provided to me reveals Mallinckrodt only had draft SOM policies that were continually being reworked and revised from the 2008-2011 time period, and no formal policies before that period.[779] These drafts relied heavily on numeric formulas that initially

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777 *See* Dempsey Deposition at 188:5-189:18.

778 *See*, Dempsey Deposition at 132:2-134:11.

779 The following are the dates and Bates number of the each of the SOM drafts from the 2008-2011 time period:

Date	*Bates number*
2008	MNK-T1_0000273894
2008	MNK-T1_0000268911
2008	MNK-T1_0000419993

1

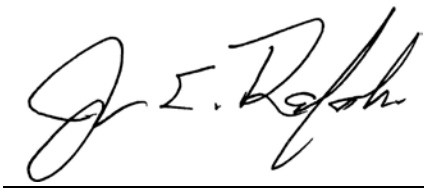
respect to the SOMs policies at Insys. However, Mr. Reimer's deposition has been stayed until after the criminal trial by the DOJ in the District of Massachusetts because Mr. Reimer is on the DOJ's witness list.

4. Nevertheless, deposition testimony by current Insys employees has confirmed that Insys failed to implement any SOM system or maintain any SOM protocols until 2018.[908]

5. This failure to conduct any sort of SOM process continued despite the fact that Insys was conscious that it habitually lost track of inventory in its downstream customers like Linden Care.[909] For other wholesalers where they did not receive inventory level reports, Insys estimated the levels. Significant differences between actual and estimated inventory levels often resulted. Many times, distributor purchases exceeded customer demand, a situation that creates a risk of diversion.

In my expert opinion, Insys failed to conduct any SOM process, even failing to track for orders of unusual size. The lack of any SOM program did not satisfy DEA requirements to detect and investigate suspicious orders. Insys failed to maintain effective controls to prevent diversion.

I reserve the right to amend or supplement my opinions in this matter considering any new or additional information.



James E. Rafalski

Date: April 15, 2019

[908] *See* Deposition of James Doroz at 53; 118; 251. *See* also Thomas Udicious Tr. at 19; 44.

[909] *See* James Doroz Tr. at 221.